UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al. Plaintiffs, v. ROBERT F. KENNEDY, JR., et al., Defendants.	Case No. 1:25-cv-10814

DECLARATION OF CHRIS PAPPAVASELIO

I, Chris Pappavaselio, an attorney admitted to practice before this Court, do hereby state the following under penalty of perjury, pursuant to 28 U.S.C. § 1746:

1. I am an Assistant Attorney General in the Office of the Attorney General for the Commonwealth of Massachusetts, and I appear on behalf of the Commonwealth of Massachusetts in this action.

2. I submit this declaration in support of Plaintiff States' Motion for a Temporary Restraining Order, pursuant to Federal Rule of Civil Procedure 65.

3. The facts set forth herein are based upon my personal knowledge or a review of the files in my possession.

4. I have attached to this declaration true and correct copies of publicly promulgated or issued documents and factual declarations, as follows:

5. Attached hereto as Exhibit 1 is Executive Order 14151, "Ending Radical Government DEI Programs and Preferencing."

6. Attached hereto as Exhibit 2 is Executive Order 14168, "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government."

7. Attached hereto as Exhibit 3 is Executive Order 14173, "Ending Illegal Discrimination and Restoring Merit-Based Opportunity."

8. Attached hereto as Exhibit 4 is a true and correct copy of a February 10, 2025 Secretarial Directive on DEI-Related Funding issued by Dorothy A. Fink, Acting Secretary of the Department of Health & Human Services.

9. Attached hereto as Exhibit 5 is a true and correct copy of a February 12, 2025 Memorandum authored by Michael S. Lauer titled "NIH Review of Agency Priorities Based on the New Administration's Goals."

10. Attached hereto as Exhibit 6 is a true and correct copy of a February 13, 2025 document titled "Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals."

11. Attached hereto as Exhibit 7 is a true and correct copy of a February 28, 2025 post on X from the Department of Government Efficiency account.

12. Attached hereto as Exhibit 8 is a true and correct copy of a March 4, 2025 document titled "Staff Guidance—Award Assessments for Alignment with Agency Priorities – March 2025."

13. Attached hereto as Exhibit 9 is a true and correct copy of a March 13, 2025 email from Michelle G. Bulls with Subject "Award Revision Guidance and List of Terminated Grants via letter on 3/12."

14. Attached hereto as Exhibit 10 is an image of March 25, 2025 notice entitled, "NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – March 2025."

15. Attached hereto as Exhibit 11 is an excerpt of the April 2024 NIH Grants Policy Statement issued by the US Department of Health and Human Services.

16. Attached hereto as Exhibit 12 is the declaration of Denise Barton and accompanying exhibits.

17. Attached hereto as Exhibit 13 is the declaration of Dr. Jason Wilder.

18. Attached hereto as Exhibit 14 is the declaration of Hala Madanat and accompanying exhibits.

19. Attached hereto as Exhibit 15 is the declaration of Ganesh Raman, Ph.D. and accompanying exhibits.

20. Attached hereto as Exhibit 16 is the declaration of Dr. Miguel Garcia-Diaz.

21. Attached hereto as Exhibit 17 is the declaration of Vasillis L. Syrmos.

22. Attached hereto as Exhibit 18 is the declaration of Darryll J. Pines and accompanying exhibits.

23. Attached hereto as Exhibit 19 is the declaration of Dr. Bruce E. Jarrell (UMB) and accompanying exhibits.

24. Attached hereto as Exhibit 20 is the declaration of John J. Farmer, Jr. and accompanying exhibits.

25. Attached hereto as Exhibit 21 is the declaration of Katie Tracy.

26. Attached hereto as Exhibit 22 is the declaration of David W. Hatchett.

27. Attached hereto as Exhibit 23 is the declaration of Timothy F. Murphy and accompanying exhibits.

28. Attached hereto as Exhibit 24 is the declaration of Scott E. Shurtleff and accompanying exhibits.

29. Attached hereto as Exhibit 25 is the declaration of Amy Hequembourg and accompanying exhibits.

30. Attached hereto as Exhibit 26 is the declaration of Bethany D. Jenkins and accompanying exhibits.

31. Attached hereto as Exhibit 27 is the declaration of Mari Ostendorf and accompanying exhibits.

32. Attached hereto as Exhibit 28 is the supplemental declaration of Mari Ostendorf and accompanying exhibits.

33. Attached hereto as Exhibit 29 is the declaration of Dorota A. Grejner-Brzezinska and accompanying exhibits.

34. Attached hereto as Exhibit 30 is the declaration of Megan A. Moreno and accompanying exhibits.

35. Attached hereto as Exhibit 31 is the declaration of Priya Nambisian.

36. Attached hereto as Exhibit 32 is the declaration of Kristian O'Connor and accompanying exhibits.

37. Attached hereto as Exhibit 33 is the declaration of Ryan Shorey.

38. Attached hereto as Exhibit 34 is the declaration of Peter G. Barr-Gillespie and accompanying exhibits.

39. Attached hereto as Exhibit 35 is the declaration of Susan Philip and accompanying exhibits.

40. Attached hereto as Exhibit 36 is the declaration of Theresa A. Maldonado.

41. Attached hereto as Exhibit 37 is the declaration of Jeremy M. Berg, Ph.D.

42. Attached hereto as Exhibit 38 is the declaration of Rafael Jaime.

Dated: April 4, 2025
Boston, MA

/s/ Chris Pappavaselio
Chris Pappavaselio
Assistant Attorney General, Honors Fellow
Office of the Attorney General

CERTIFICATE OF SERVICE

I, Chris Pappavaselio, certify that on April 4, 2025, I provided a copy of the foregoing document and its attachments to the following individuals at the U.S. Department of Justice:

Brad Rosenberg
Special Counsel
Federal Programs Branch
U.S. Department of Justice
Brad.Rosenberg@usdoj.gov

Abraham George
Chief, Civil Division
District of Massachusetts
abraham.george@usdoj.gov

Rayford Farquhar
Chief, Defensive Litigation, Civil Division
U.S. Attorney's Office for the District of Massachusetts
rayford.farquhar@usdoj.gov

/s/ Chris Pappavaselio
Chris Pappavaselio
Assistant Attorney General

EXHIBIT 1

Presidential Documents

Executive Order 14151 of January 20, 2025

Ending Radical and Wasteful Government DEI Programs and Preferencing

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose and Policy.* The Biden Administration forced illegal and immoral discrimination programs, going by the name ''diversity, equity, and inclusion'' (DEI), into virtually all aspects of the Federal Government, in areas ranging from airline safety to the military. This was a concerted effort stemming from President Biden's first day in office, when he issued Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.''

Pursuant to Executive Order 13985 and follow-on orders, nearly every Federal agency and entity submitted ''Equity Action Plans'' to detail the ways that they have furthered DEIs infiltration of the Federal Government. The public release of these plans demonstrated immense public waste and shameful discrimination. That ends today. Americans deserve a government committed to serving every person with equal dignity and respect, and to expending precious taxpayer resources only on making America great.

Sec. 2. *Implementation.* (a) The Director of the Office of Management and Budget (OMB), assisted by the Attorney General and the Director of the Office of Personnel Management (OPM), shall coordinate the termination of all discriminatory programs, including illegal DEI and ''diversity, equity, inclusion, and accessibility'' (DEIA) mandates, policies, programs, preferences, and activities in the Federal Government, under whatever name they appear. To carry out this directive, the Director of OPM, with the assistance of the Attorney General as requested, shall review and revise, as appropriate, all existing Federal employment practices, union contracts, and training policies or programs to comply with this order. Federal employment practices, including Federal employee performance reviews, shall reward individual initiative, skills, performance, and hard work and shall not under any circumstances consider DEI or DEIA factors, goals, policies, mandates, or requirements.

(b) Each agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM, as appropriate, shall take the following actions within sixty days of this order:

(i) terminate, to the maximum extent allowed by law, all DEI, DEIA, and ''environmental justice'' offices and positions (including but not limited to ''Chief Diversity Officer'' positions); all ''equity action plans,'' ''equity'' actions, initiatives, or programs, ''equity-related'' grants or contracts; and all DEI or DEIA performance requirements for employees, contractors, or grantees.

(ii) provide the Director of the OMB with a list of all:

(A) agency or department DEI, DEIA, or ''environmental justice'' positions, committees, programs, services, activities, budgets, and expenditures in existence on November 4, 2024, and an assessment of whether these positions, committees, programs, services, activities, budgets, and expenditures have been misleadingly relabeled in an attempt to preserve their pre-November 4, 2024 function;

(B) Federal contractors who have provided DEI training or DEI training materials to agency or department employees; and

(C) Federal grantees who received Federal funding to provide or advance DEI, DEIA, or ''environmental justice'' programs, services, or activities since January 20, 2021.

(iii) direct the deputy agency or department head to:

(A) assess the operational impact (e.g., the number of new DEI hires) and cost of the prior administration's DEI, DEIA, and ''environmental justice'' programs and policies; and

(B) recommend actions, such as Congressional notifications under 28 U.S.C. 530D, to align agency or department programs, activities, policies, regulations, guidance, employment practices, enforcement activities, contracts (including set-asides), grants, consent orders, and litigating positions with the policy of equal dignity and respect identified in section 1 of this order. The agency or department head and the Director of OMB shall jointly ensure that the deputy agency or department head has the authority and resources needed to carry out this directive.

(c) To inform and advise the President, so that he may formulate appropriate and effective civil-rights policies for the Executive Branch, the Assistant to the President for Domestic Policy shall convene a monthly meeting attended by the Director of OMB, the Director of OPM, and each deputy agency or department head to:

(i) hear reports on the prevalence and the economic and social costs of DEI, DEIA, and ''environmental justice'' in agency or department programs, activities, policies, regulations, guidance, employment practices, enforcement activities, contracts (including set-asides), grants, consent orders, and litigating positions;

(ii) discuss any barriers to measures to comply with this order; and

(iii) monitor and track agency and department progress and identify potential areas for additional Presidential or legislative action to advance the policy of equal dignity and respect.

Sec. 3. *Severability.* If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected.

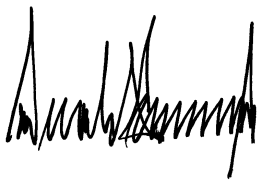
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 20, 2025.

[FR Doc. 2025–01953
Filed 1–28–25; 8:45 am]
Billing code 3395–F4–P

EXHIBIT 2

Presidential Documents

Executive Order 14168 of January 20, 2025

Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 7301 of title 5, United States Code, it is hereby ordered:

Section 1. *Purpose.* Across the country, ideologues who deny the biological reality of sex have increasingly used legal and other socially coercive means to permit men to self-identify as women and gain access to intimate single-sex spaces and activities designed for women, from women's domestic abuse shelters to women's workplace showers. This is wrong. Efforts to eradicate the biological reality of sex fundamentally attack women by depriving them of their dignity, safety, and well-being. The erasure of sex in language and policy has a corrosive impact not just on women but on the validity of the entire American system. Basing Federal policy on truth is critical to scientific inquiry, public safety, morale, and trust in government itself.

This unhealthy road is paved by an ongoing and purposeful attack against the ordinary and longstanding use and understanding of biological and scientific terms, replacing the immutable biological reality of sex with an internal, fluid, and subjective sense of self unmoored from biological facts. Invalidating the true and biological category of ''woman'' improperly transforms laws and policies designed to protect sex-based opportunities into laws and policies that undermine them, replacing longstanding, cherished legal rights and values with an identity-based, inchoate social concept.

Accordingly, my Administration will defend women's rights and protect freedom of conscience by using clear and accurate language and policies that recognize women are biologically female, and men are biologically male.

Sec. 2. *Policy and Definitions.* It is the policy of the United States to recognize two sexes, male and female. These sexes are not changeable and are grounded in fundamental and incontrovertible reality. Under my direction, the Executive Branch will enforce all sex-protective laws to promote this reality, and the following definitions shall govern all Executive interpretation of and application of Federal law and administration policy:

(a) ''Sex'' shall refer to an individual's immutable biological classification as either male or female. ''Sex'' is not a synonym for and does not include the concept of ''gender identity.''

(b) ''Women'' or ''woman'' and ''girls'' or ''girl'' shall mean adult and juvenile human females, respectively.

(c) ''Men'' or ''man'' and ''boys'' or ''boy'' shall mean adult and juvenile human males, respectively.

(d) ''Female'' means a person belonging, at conception, to the sex that produces the large reproductive cell.

(e) ''Male'' means a person belonging, at conception, to the sex that produces the small reproductive cell.

(f) ''Gender ideology'' replaces the biological category of sex with an ever-shifting concept of self-assessed gender identity, permitting the false claim that males can identify as and thus become women and vice versa, and requiring all institutions of society to regard this false claim as true.

Gender ideology includes the idea that there is a vast spectrum of genders that are disconnected from one's sex. Gender ideology is internally inconsistent, in that it diminishes sex as an identifiable or useful category but nevertheless maintains that it is possible for a person to be born in the wrong sexed body.

(g) ''Gender identity'' reflects a fully internal and subjective sense of self, disconnected from biological reality and sex and existing on an infinite continuum, that does not provide a meaningful basis for identification and cannot be recognized as a replacement for sex.

Sec. 3. *Recognizing Women Are Biologically Distinct From Men.* (a) Within 30 days of the date of this order, the Secretary of Health and Human Services shall provide to the U.S. Government, external partners, and the public clear guidance expanding on the sex-based definitions set forth in this order.

(b) Each agency and all Federal employees shall enforce laws governing sex-based rights, protections, opportunities, and accommodations to protect men and women as biologically distinct sexes. Each agency should therefore give the terms ''sex'', ''male'', ''female'', ''men'', ''women'', ''boys'' and ''girls'' the meanings set forth in section 2 of this order when interpreting or applying statutes, regulations, or guidance and in all other official agency business, documents, and communications.

(c) When administering or enforcing sex-based distinctions, every agency and all Federal employees acting in an official capacity on behalf of their agency shall use the term ''sex'' and not ''gender'' in all applicable Federal policies and documents.

(d) The Secretaries of State and Homeland Security, and the Director of the Office of Personnel Management, shall implement changes to require that government-issued identification documents, including passports, visas, and Global Entry cards, accurately reflect the holder's sex, as defined under section 2 of this order; and the Director of the Office of Personnel Management shall ensure that applicable personnel records accurately report Federal employees' sex, as defined by section 2 of this order.

(e) Agencies shall remove all statements, policies, regulations, forms, communications, or other internal and external messages that promote or otherwise inculcate gender ideology, and shall cease issuing such statements, policies, regulations, forms, communications or other messages. Agency forms that require an individual's sex shall list male or female, and shall not request gender identity. Agencies shall take all necessary steps, as permitted by law, to end the Federal funding of gender ideology.

(f) The prior Administration argued that the Supreme Court's decision in *Bostock* v. *Clayton County* (2020), which addressed Title VII of the Civil Rights Act of 1964, requires gender identity-based access to single-sex spaces under, for example, Title IX of the Educational Amendments Act. This position is legally untenable and has harmed women. The Attorney General shall therefore immediately issue guidance to agencies to correct the misapplication of the Supreme Court's decision in *Bostock* v. *Clayton County* (2020) to sex-based distinctions in agency activities. In addition, the Attorney General shall issue guidance and assist agencies in protecting sex-based distinctions, which are explicitly permitted under Constitutional and statutory precedent.

(g) Federal funds shall not be used to promote gender ideology. Each agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology.

Sec. 4. *Privacy in Intimate Spaces.* (a) The Attorney General and Secretary of Homeland Security shall ensure that males are not detained in women's prisons or housed in women's detention centers, including through amendment, as necessary, of Part 115.41 of title 28, Code of Federal Regulations and interpretation guidance regarding the Americans with Disabilities Act.

(b) The Secretary of Housing and Urban Development shall prepare and submit for notice and comment rulemaking a policy to rescind the final rule entitled ''Equal Access in Accordance with an Individual's Gender Identity in Community Planning and Development Programs'' of September 21, 2016, 81 FR 64763, and shall submit for public comment a policy protecting women seeking single-sex rape shelters.

(c) The Attorney General shall ensure that the Bureau of Prisons revises its policies concerning medical care to be consistent with this order, and shall ensure that no Federal funds are expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex.

(d) Agencies shall effectuate this policy by taking appropriate action to ensure that intimate spaces designated for women, girls, or females (or for men, boys, or males) are designated by sex and not identity.

Sec. 5. *Protecting Rights.* The Attorney General shall issue guidance to ensure the freedom to express the binary nature of sex and the right to single-sex spaces in workplaces and federally funded entities covered by the Civil Rights Act of 1964. In accordance with that guidance, the Attorney General, the Secretary of Labor, the General Counsel and Chair of the Equal Employment Opportunity Commission, and each other agency head with enforcement responsibilities under the Civil Rights Act shall prioritize investigations and litigation to enforce the rights and freedoms identified.

Sec. 6. *Bill Text.* Within 30 days of the date of this order, the Assistant to the President for Legislative Affairs shall present to the President proposed bill text to codify the definitions in this order.

Sec. 7. *Agency Implementation and Reporting.* (a) Within 120 days of the date of this order, each agency head shall submit an update on implementation of this order to the President, through the Director of the Office of Management and Budget. That update shall address:

(i) changes to agency documents, including regulations, guidance, forms, and communications, made to comply with this order; and

(ii) agency-imposed requirements on federally funded entities, including contractors, to achieve the policy of this order.

(b) The requirements of this order supersede conflicting provisions in any previous Executive Orders or Presidential Memoranda, including but not limited to Executive Orders 13988 of January 20, 2021, 14004 of January 25, 2021, 14020 and 14021 of March 8, 2021, and 14075 of June 15, 2022. These Executive Orders are hereby rescinded, and the White House Gender Policy Council established by Executive Order 14020 is dissolved.

(c) Each agency head shall promptly rescind all guidance documents inconsistent with the requirements of this order or the Attorney General's guidance issued pursuant to this order, or rescind such parts of such documents that are inconsistent in such manner. Such documents include, but are not limited to:

(i) ''The White House Toolkit on Transgender Equality'';

(ii) the Department of Education's guidance documents including:

(A) ''2024 Title IX Regulations: Pointers for Implementation'' (July 2024);

(B) ''U.S. Department of Education Toolkit: Creating Inclusive and Nondiscriminatory School Environments for LGBTQI+ Students'';

(C) ''U.S. Department of Education Supporting LGBTQI+ Youth and Families in School'' (June 21, 2023);

(D) ''Departamento de Educación de EE.UU. Apoyar a los jóvenes y familias LGBTQI+ en la escuela'' (June 21, 2023);

(E) ''Supporting Intersex Students: A Resource for Students, Families, and Educators'' (October 2021);

(F) ''Supporting Transgender Youth in School'' (June 2021);

(G) ''Letter to Educators on Title IX's 49th Anniversary'' (June 23, 2021);

(H) ''Confronting Anti-LGBTQI+ Harassment in Schools: A Resource for Students and Families'' (June 2021);

(I) ''Enforcement of Title IX of the Education Amendments of 1972 With Respect to Discrimination Based on Sexual Orientation and Gender Identity in Light of Bostock v. Clayton County'' (June 22, 2021);

(J) ''Education in a Pandemic: The Disparate Impacts of COVID–19 on America's Students'' (June 9, 2021); and

(K) ''Back-to-School Message for Transgender Students from the U.S. Depts of Justice, Education, and HHS'' (Aug. 17, 2021);

(iii) the Attorney General's Memorandum of March 26, 2021 entitled ''Application of *Bostock* v. *Clayton County* to Title IX of the Education Amendments of 1972''; and

(iv) the Equal Employment Opportunity Commission's ''Enforcement Guidance on Harassment in the Workplace'' (April 29, 2024).

Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

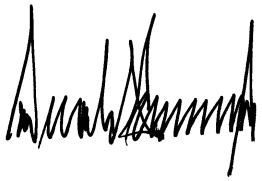
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected thereby.



THE WHITE HOUSE,
January 20, 2025.

[FR Doc. 2025–02090
Filed 1–29–25; 11:15 am]
Billing code 3395–F4–P

EXHIBIT 3

Presidential Documents

Executive Order 14173 of January 21, 2025

Ending Illegal Discrimination and Restoring Merit-Based Opportunity

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose.* Longstanding Federal civil-rights laws protect individual Americans from discrimination based on race, color, religion, sex, or national origin. These civil-rights protections serve as a bedrock supporting equality of opportunity for all Americans. As President, I have a solemn duty to ensure that these laws are enforced for the benefit of all Americans.

Yet today, roughly 60 years after the passage of the Civil Rights Act of 1964, critical and influential institutions of American society, including the Federal Government, major corporations, financial institutions, the medical industry, large commercial airlines, law enforcement agencies, and institutions of higher education have adopted and actively use dangerous, demeaning, and immoral race- and sex-based preferences under the guise of so-called ''diversity, equity, and inclusion'' (DEI) or ''diversity, equity, inclusion, and accessibility'' (DEIA) that can violate the civil-rights laws of this Nation.

Illegal DEI and DEIA policies not only violate the text and spirit of our longstanding Federal civil-rights laws, they also undermine our national unity, as they deny, discredit, and undermine the traditional American values of hard work, excellence, and individual achievement in favor of an unlawful, corrosive, and pernicious identity-based spoils system. Hard-working Americans who deserve a shot at the American Dream should not be stigmatized, demeaned, or shut out of opportunities because of their race or sex.

These illegal DEI and DEIA policies also threaten the safety of American men, women, and children across the Nation by diminishing the importance of individual merit, aptitude, hard work, and determination when selecting people for jobs and services in key sectors of American society, including all levels of government, and the medical, aviation, and law-enforcement communities. Yet in case after tragic case, the American people have witnessed first-hand the disastrous consequences of illegal, pernicious discrimination that has prioritized how people were born instead of what they were capable of doing.

The Federal Government is charged with enforcing our civil-rights laws. The purpose of this order is to ensure that it does so by ending illegal preferences and discrimination.

Sec. 2. *Policy.* It is the policy of the United States to protect the civil rights of all Americans and to promote individual initiative, excellence, and hard work. I therefore order all executive departments and agencies (agencies) to terminate all discriminatory and illegal preferences, mandates, policies, programs, activities, guidance, regulations, enforcement actions, consent orders, and requirements. I further order all agencies to enforce our longstanding civil-rights laws and to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities.

Sec. 3. *Terminating Illegal Discrimination in the Federal Government.* (a) The following executive actions are hereby revoked:

(i) Executive Order 12898 of February 11, 1994 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations);

(ii) Executive Order 13583 of August 18, 2011 (Establishing a Coordinated Government-wide Initiative to Promote Diversity and Inclusion in the Federal Workforce);

(iii) Executive Order 13672 of July 21, 2014 (Further Amendments to Executive Order 11478, Equal Employment Opportunity in the Federal Government, and Executive Order 11246, Equal Employment Opportunity); and

(iv) The Presidential Memorandum of October 5, 2016 (Promoting Diversity and Inclusion in the National Security Workforce).

(b) The Federal contracting process shall be streamlined to enhance speed and efficiency, reduce costs, and require Federal contractors and subcontractors to comply with our civil-rights laws. Accordingly:

(i) Executive Order 11246 of September 24, 1965 (Equal Employment Opportunity), is hereby revoked. For 90 days from the date of this order, Federal contractors may continue to comply with the regulatory scheme in effect on January 20, 2025.

(ii) The Office of Federal Contract Compliance Programs within the Department of Labor shall immediately cease:

(A) Promoting ''diversity'';

(B) Holding Federal contractors and subcontractors responsible for taking ''affirmative action''; and

(C) Allowing or encouraging Federal contractors and subcontractors to engage in workforce balancing based on race, color, sex, sexual preference, religion, or national origin.

(iii) In accordance with Executive Order 13279 of December 12, 2002 (Equal Protection of the Laws for Faith-Based and Community Organizations), the employment, procurement, and contracting practices of Federal contractors and subcontractors shall not consider race, color, sex, sexual preference, religion, or national origin in ways that violate the Nation's civil rights laws.

(iv) The head of each agency shall include in every contract or grant award:

(A) A term requiring the contractual counterparty or grant recipient to agree that its compliance in all respects with all applicable Federal anti-discrimination laws is material to the government's payment decisions for purposes of section 3729(b)(4) of title 31, United States Code; and

(B) A term requiring such counterparty or recipient to certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws.

(c) The Director of the Office of Management and Budget (OMB), with the assistance of the Attorney General as requested, shall:

(i) Review and revise, as appropriate, all Government-wide processes, directives, and guidance;

(ii) Excise references to DEI and DEIA principles, under whatever name they may appear, from Federal acquisition, contracting, grants, and financial assistance procedures to streamline those procedures, improve speed and efficiency, lower costs, and comply with civil-rights laws; and

(iii) Terminate all ''diversity,'' ''equity,'' ''equitable decision-making,'' ''equitable deployment of financial and technical assistance,'' ''advancing equity,'' and like mandates, requirements, programs, or activities, as appropriate.

Sec. 4. *Encouraging the Private Sector to End Illegal DEI Discrimination and Preferences.* (a) The heads of all agencies, with the assistance of the

Attorney General, shall take all appropriate action with respect to the operations of their agencies to advance in the private sector the policy of individual initiative, excellence, and hard work identified in section 2 of this order.

(b) To further inform and advise me so that my Administration may formulate appropriate and effective civil-rights policy, the Attorney General, within 120 days of this order, in consultation with the heads of relevant agencies and in coordination with the Director of OMB, shall submit a report to the Assistant to the President for Domestic Policy containing recommendations for enforcing Federal civil-rights laws and taking other appropriate measures to encourage the private sector to end illegal discrimination and preferences, including DEI. The report shall contain a proposed strategic enforcement plan identifying:

(i) Key sectors of concern within each agency's jurisdiction;

(ii) The most egregious and discriminatory DEI practitioners in each sector of concern;

(iii) A plan of specific steps or measures to deter DEI programs or principles (whether specifically denominated ''DEI'' or otherwise) that constitute illegal discrimination or preferences. As a part of this plan, each agency shall identify up to nine potential civil compliance investigations of publicly traded corporations, large non-profit corporations or associations, foundations with assets of 500 million dollars or more, State and local bar and medical associations, and institutions of higher education with endowments over 1 billion dollars;

(iv) Other strategies to encourage the private sector to end illegal DEI discrimination and preferences and comply with all Federal civil-rights laws;

(v) Litigation that would be potentially appropriate for Federal lawsuits, intervention, or statements of interest; and

(vi) Potential regulatory action and sub-regulatory guidance.

Sec. 5. *Other Actions.* Within 120 days of this order, the Attorney General and the Secretary of Education shall jointly issue guidance to all State and local educational agencies that receive Federal funds, as well as all institutions of higher education that receive Federal grants or participate in the Federal student loan assistance program under Title IV of the Higher Education Act, 20 U.S.C. 1070 *et seq.,* regarding the measures and practices required to comply with *Students for Fair Admissions, Inc.* v. *President and Fellows of Harvard College,* 600 U.S. 181 (2023).

Sec. 6. *Severability.* If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected thereby.

Sec. 7. *Scope.* (a) This order does not apply to lawful Federal or private-sector employment and contracting preferences for veterans of the U.S. armed forces or persons protected by the Randolph-Sheppard Act, 20 U.S.C. 107 *et seq.*

(b) This order does not prevent State or local governments, Federal contractors, or Federally-funded State and local educational agencies or institutions of higher education from engaging in First Amendment-protected speech.

(c) This order does not prohibit persons teaching at a Federally funded institution of higher education as part of a larger course of academic instruction from advocating for, endorsing, or promoting the unlawful employment or contracting practices prohibited by this order.

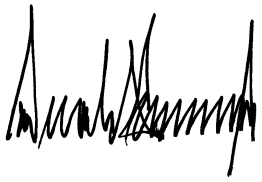
Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to and does not create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 21, 2025.

[FR Doc. 2025–02097
Filed 1–30–25; 8:45 am]
Billing code 3395–F4–P

EXHIBIT 4

Appendix 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

EXHIBIT 5

National Institutes of Health
Office of Extramural Research

Date: February 12, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.12 09:26:33 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S Date: 2025.02.12 09:40:52 -05'00'
NIH Chief Grants Management Officer

Subject: NIH Review of Agency Priorities Based on the New Administration's Goals

NIH is in the process of reevaluating the agency's priorities based on the goals of the new administration. NIH will effectuate the administration's goals over time, but given recent court orders, this cannot be a factor in IC funding decisions at this time. In consultation with NIH leadership and with the Office of General Counsel (OGC), we recognize that NIH programs fall under recently issued Temporary Restraining Orders (*New York et al. v. U.S. Office of Management and Budget* and *Commonwealth of Massachusetts et al. v. National Institutes of Health et al* see attached). Therefore, with this memo, IC CGMOs are authorized, along with their respective grants management staff, to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements (previously cleared through Office of Extramural Research) grants. Until further notice, as awards are issued, ICs must follow their existing FY25 IC funding policies and use the previously approved negotiated indirect cost rates. Additional details on future funding actions related to the agency's goals will be provided under a separate memo.

Attachments

1. Temporary Restraining Order, *New York et al. v. U.S. Office of Management and Budget* (Jan. 31, 2025)
2. Court Order Questions – HHS OGC Responses (February 4, 2025)
3. Temporary Restraining Order, *Commonwealth of Massachusetts et al. v. National Institutes of Health et al.,* (February 10, 2025)
4. Order Enforcing TRO, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)
5. Office of General Counsel Note, *New York et al. v. U.S. Office of Management and Budget* (February 10, 2025)

EXHIBIT 6

National Institutes of Health
Office of Extramural Research

Date: February 13, 2025

To: Institute and Center Chief Grants Management Officers (IC CGMOs)

From: Michael S. Lauer, MD Michael S. Lauer -S Digitally signed by Michael S. Lauer -S Date: 2025.02.13 15:06:52 -05'00'
Deputy Director for Extramural Research, National Institutes of Health (NIH)

Michelle G. Bulls Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S Date: 2025.02.13 15:11:19 -05'00'
NIH Chief Grants Management Officer

Subject: Supplemental Guidance to Memo Entitled- NIH Review of Agency Priorities Based on the New Administration's Goals

The Office of Extramural Research is issuing supplemental guidance to the memo, dated February 12, 2025, to Institute and Center (IC) Chief Grants Management Officers (CGMOs) and their respective staff to issue hard funding restrictions on awards and within the Payment Management System (PMS)/Program Support Center (PSC) on awards where the program promotes or takes part in diversity, equity, and includsion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics. The restriction requirement applies to new and continuation awards made on or after February 14, 2025. If the sole purpose of the grant, cooperative agreement, other transaction award (including modifications), or supplement supports DEI activities, then the award must be fully restricted. The restrictions will remain in place until the agency conducts an internal review for payment integrity. Such review shall include, but not be limited to a review for fraud, waste, abuse, of all grants, cooperative agreements, and Other Transactions that determines the funding of the activities/program are in the best interest of the government and consistent with current policy priorities.

Attachments

1. Memo NIH Review of Agency Priorities Based on the New Administration's Goals, February 12, 2025

2. UPDATE - Temporary Restraining Order in State of New York et al. v. Trump et al., 1:25-cv-00039 (D.R.I.), February 12, 2025

3. Secretarial Directive on DEI Related Funding, February 10, 2025

EXHIBIT 7

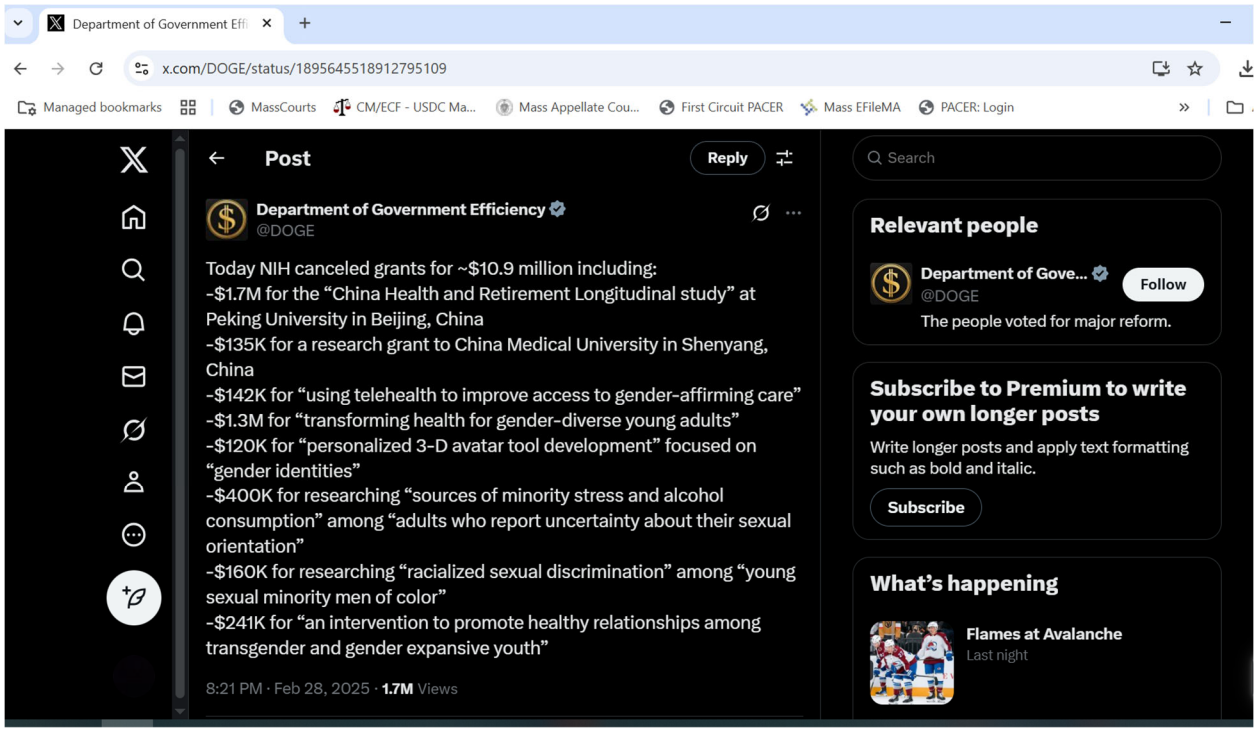

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@DOGE
Today NIH canceled grants for ~$10.9 million including:
-$1.7M for the "China Health and Retirement Longitudinal study" at Peking University in Beijing, China
-$135K for a research grant to China Medical University in Shenyang, China
-$142K for "using telehealth to improve access to gender-affirming care"
-$1.3M for "transforming health for gender-diverse young adults"
-$120K for "personalized 3-D avatar tool development" focused on "gender identities"
-$400K for researching "sources of minority stress and alcohol consumption" among "adults who report uncertainty about their sexual orientation"
-$160K for researching "racialized sexual discrimination" among "young sexual minority men of color"
-$241K for "an intervention to promote healthy relationships among transgender and gender expansive youth"
8:21 PM · Feb 28, 2025 · 1.7M Views
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EXHIBIT 8

Staff Guidance –Award Assessments for Alignment with Agency Priorities - March 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims assess whether the proposed project contains any DEI research activities or DEI language that give the perception that NIH funds can be used to support these activities. To avoid issuing awards, in error, that support DEI activities ICs must take care to completely excise all DEI activities using the following categories.

Category 1: The sole purpose of the project is DEI related (e.g., diversity supplements or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that was unpublished as outlined above.

- Action: ICs must not issue the award.

Category 2: Project partially supports DEI activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope) this means DEI activities are ancillary to the purpose of the project. In some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the DEI Restriction Term of Award in Section IV of the Notice of Award, no exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Action 1: Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file.
- Action 2: Once the IC and the applicant/recipient have reached an agreement, issue the award and include the DEI Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.
    - **Note:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the DEI related activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Appendix 2.

Category 3: Project does not support DEI activities, but may contain language related to DEI (e.g., statement regarding institutional commitment to diversity in the 'Facilities & Other Resources' attachment and terminology related to structural racism—this is not all-inclusive).

- Action 1: Funding IC must request an updated application/RPPR with the DEI language removed.
- Action 2: Once the language has been removed, the IC may proceed with issuing the award.

Category 4: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

The Department of Health and Human Services has an obligation to ensure that taxpayer dollars are used to advance the best interests of the government. This includes avoiding the expenditure of federal funds on programs, or with contractors or vendors, that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Contracts and grants that support DEI and similar discriminatory programs can violate Federal civil rights law and are inconsistent with the Department's policy of improving the health and well-being of all Americans.

These contracts and grants can cause serious programmatic failures and yet it is currently impossible to access sufficient information from a centralized source within the Department of Health and Human Services to assess them. Specifically, there is no one method to determine whether payments the agency is making to contractors, vendors, and grantees for functions related to DEI and similar programs are contributing to the serious problems and acute harms DEI initiatives may pose to the Department's compliance with Federal civil rights law as well as the Department's policy of improving the health and well-being of all Americans. It is also currently impossible to assess whether payments the Department is making are free from fraud, abuse, and duplication, as well as to assess whether current contractual arrangements, vendor agreements, and grant awards related to these functions are in the best interests of the United States. *See* FAR 12.403(b), 49.101; 45 C.F.R. § 75.371-372. Finally, it is also impossible to determine with current systems whether current contracts and grant awards are tailored to ameliorate these specific problems and the broader problem of DEI and similar programs rather than exacerbate them. The Department has an obligation to ensure that no taxpayer dollars are lost to abuse or expended on anything other than advancing the best interests of the nation.

For these reasons, pursuant to, among other authorities, FAR 12.403(b) and 49.101 and 45 C.F.R. § 75.371- 372, the Secretary of Health and Human Services hereby DIRECTS as follows:

> **Agency personnel shall briefly pause all payments made to contractors, vendors, and grantees related to DEI and similar programs for internal review for payment integrity. Such review shall include but not be limited to a review for fraud, waste, abuse, and a review of the overall contracts and grants to determine whether those contracts or grants are in the best interest of the government and consistent with current policy priorities. In addition, if after review the Department has determined that a contract is inconsistent with Department priorities and no longer in the interest of the government, such contracts may be terminated pursuant to the Department's authority to terminate for convenience contracts that are not "in the best interests of the Government," see FAR 49.101(b); 12.403(b). Furthermore, grants may be terminated in accordance with federal law.**

This Directive shall be implemented through the Department's contracts and payment management systems by personnel with responsibility for such systems who shall, in doing so, comply with all notice and procedural requirements in each affected award, agreement, or other instrument. Whenever a DEI or similar contract or grant is paused for review, Department personnel shall immediately send such payment to Scott Rowell, Deputy Chief of Staff for Operations, for prompt review to determine whether or not the payment is appropriate and should be made. Payments on paused contracts shall remain paused and already terminated contracts shall remain terminated pending completion of that review to the maximum extent permitted by law and all applicable notice and procedural requirements in the affected award, agreement, or other instrument.

I thank you for your attention to this matter, as well as your efforts to ensure that no taxpayer dollars are misspent.

Dorothy A. Fink

Dorothy A. Fink, M.D., Acting Secretary

Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC.

- Issue a revised NOA.
    - Change the budget and project period end dates to match the date of the termination letter.
    - Check PMS, determine amount of funds remaining, and deobligate the amount reflected in PMS when revising the NOA. Note: This applies to Multi-Year Funded Awards, as well. Work with FFR-C if you have questions regarding deobligating funds to avoid placing the recipient in debt collection.
    - Remove all future years from the project, where applicable. If the grant is in a no cost extension, and the HHS requests a termination, the project must be terminated
    - Use the following termination term: This award related to [select the appropriate example relevant to your project by choosing one of the highlighted examples DEI, China, or Transgender issues] no longer effectuates agency priorities. It is the policy of NIH not to further prioritize these research programs. Therefore, the award is terminated. [Refer to Appendix 3 for language provided to NIH by HHS.] Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR)) within 120 days of the end of this grant to avoid unilateral closeout.
    - Insert restriction language that allows for the recipients to use a portion of funds to support the health and safety of patients and orderly closeout of the project.
        - Sample language for use: "Funds in the amount of $xxxxxxx [insert $ amount total cost] may be used to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered."
- Appeals language must be used (prior to October 1, 2025):
    - NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This letter represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli.

      Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.
- Termination actions taken based on agency priorities do not require appeals language because the action was not based on administrative nor programmatic noncompliance

Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports.

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Transgender issues: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Appendix 4 – Approved Term – Use for all Category 2 awards, i.e., renegotiated aims and associated budgets. Approval embedded below. ICs should use this term in the IC specific award conditions

Term and Condition of Award

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including Diversity Equity and Inclusion (DEI) research or DEI-related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes DEI or has questions regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

Approval email from Dr. Memoli (Acting Director, NIH) on Friday, February 28, 2025.

From:	Memoli, Matthew (NIH/OD) [E]
To:	Bundesen, Liza (NIH/OD) [E]
Cc:	Bulls, Michelle G. (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Butler, Benjamin (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Subject:	Re: Clean Version of DEI Restriction Term - Final
Date:	Friday, February 28, 2025 2:54:19 PM

approved

Matt

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From: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>
Sent: Friday, February 28, 2025 2:53:21 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Butler, Benjamin (NIH/OD) [E] <butlerben@mail.nih.gov>; Jacobs, Anna (NIH/OD) [E] <anna.jacobs2@nih.gov>; Burklow, John (NIH/OD) [E] <burklowj@od.nih.gov>
Subject: Clean Version of DEI Restriction Term - Final

Hi Matt,

Attached is the term and condition of award for your approval. Please let us know if you approve and we will implement.

Thank you,
Liza

EXHIBIT 9

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Thursday, March 13, 2025 4:04 PM
To: Chief GMOs <ChiefGMOs@mail.nih.gov>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>
Subject: Award Revision Guidance and List of Terminated Grants via letter on 3/12

Chiefs,

Attached are two items: 1) updated categories for you to use when issuing NOAs to officially terminate the awards where letters were issued, and 2) the list of termination letters that were issued yesterday. Please revise your NOAs related to the attached list by next **Wednesday, March 13, 2025, cob**. It is extremely important that issue the revised awards timely. If there are delays, please let me know and we can try to help somehow/some way. I appreciate you all.

Please save this guidance until we can clear the updated staff guidance, and you will need this to issue revised awards. Note: If your IC is not listed on the attached spreadsheet – no action is required, at this time.

Guidance for IC staff to use when terminating awards identified by HHS or the IC due to DEI or other agency priorities.

- Issue a revised NOA.
    1. Change the budget and project period end dates to match the date of the termination letter.
    2. OPERA will place a hard funds restriction on all documents within the excel spreadsheet. Do not deobigate any funds when you issue the revised award to terminate the projects. If there are no animals and humans, FFR-C will deobligate the awards after the Final FFRs are submitted. No deoblgiation actions required from the ICs.
    3. Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated.
    4. Termination Term to be used **DELETE THE OLD TERM RELATED TO DOLLAR AMOUNTS FOR HARD FUNDS RESTRICTIONS – IT IS NO LONGER APPLICABLE**.

        It is the policy of NIH not to prioritize [insert termination category language]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research

Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Thanks,
Michelle

Termination Categories

- China: Bolstering Chinese universities does not enhance the American people's quality of life or improve America's position in the world. On the contrary, funding research in China contravenes American national-security interests and hinders America's foreign-policy objectives.
- DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.
- Gender: Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
- Vaccine Hesitancy: It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

EXHIBIT 10

INTERNAL: NOT FOR DISTRIBUTION OUTSIDE THE GOVERNMENT

NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities- March 2025

Issue Date: March 25, 2025

Background

This staff guidance rescinds the guidance provided in the February 13, 2025, memo to IC Chief Grants Management Officers entitled Supplemental Guidance – NIH Review of Agency Priorities Based on the New Administration's Goals. In accordance with the Secretarial Directive on DEI Related Funding (Appendix 1), NIH will no longer prioritize research and research training programs that focus on Diversity, Equity and Inclusion (DEI). Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas must follow the appeals guidance below. All other terminations for noncompliance require, always, appeal language.

Prior to issuing all awards (competing and non-competing) or approving requests for carryover, ICs must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI, gender identity or other research activities that are not an NIH/HHS priority/ authority. To avoid issuing awards, in error, that support these activities ICs must take care to completely excise all non-priority activities using the following categories.

ICs should review the current application/RPPR under consideration, only. ICs should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted. Categories 1-3 are IC determinations not those ordered by HHS.

Category 1: The sole purpose of the project is related to an area that is no longer an NIH/HHS priority/ authority (e.g., diversity supplements, diversity fellowships, or conference grant where the purpose of the meeting is diversity), and/or the application was received in response to a NOFO that has been unpublished due to its focus on activities that are no longer an NIH/HHS priority/authority. This applies to all projects, including phased awards, etc.

- **Action:** ICs must not issue the award (competing or non-competing).
- For ongoing projects where NIH will not issue the next Type 5 (IC determination not HHS list), the IC must:
  - Issue a revised award to remove all outyears.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (access limited to CGMOs).
  - Include the following term in the revised NOA:

Term of Award:

It is the policy of NIH not to prioritize research programs related to [insert category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to

submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Check PMS to determine amount of funds remaining, and if funds are available request a hard funds restriction of all funds except $1 in PMS.

- **No cost extension requests:** For second and third NCE's, ICs must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS priority/authority and, if so, issue an award to end the grant project (use disapproved extension term below). If the non-NIH/HHS priority/authority research activities are ancillary to the project, approve the extension (use approved extension term below). Reminder – even if a grant project is in an NCE, IC staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly closeout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

  - ICs may use the following term of award when approving/disapproving NCEs:
    - **Term of Award (approved extension):** The no-cost extension has been approved for this project to support orderly closeout of the project, only. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs. Any funds used to support such activities will result in a disallowance of costs, and funds will be recovered.
    - **Term of Award (disapproved extension)**: The no cost extension request for this project has been denied. Please proceed with orderly closeout of the project. NIH grant funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), gender identity, etc.] research or research training activities or programs.

Category 2: Project partially supports non-NIH/HHS priority/authority activities (i.e., the project may still be viable if those aims or activities are negotiated out, without significant changes from the original peer-reviewed scope). This means the non-NIH/HHS priority/authority activities are ancillary to the purpose of the project, in some cases, not readily visible. This category requires a scientific assessment and requires the GM to use the Restriction Term of Award in Section IV of

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the Notice of Award. No exceptions will be allowed without a deviation from the Office of Policy for Extramural Research Administration (OPERA)/Office of Extramural Research (OER).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding IC must negotiate with the applicant/recipient to address the activities that are non-compliant, along with the associated funds that support those activities, obtain revised aims and budgets, and document the changes in the grant file. The recipient/awardee cannot rebudget these funds, they must be recovered by the IC. OPERA is consulting with eRA on options to collect these application updates in a structured format.
  - Sample language for requesting application updates from the AOR: It is the policy of NIH not to prioritize [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa.] [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section [XXXX] of your application. Please work with the PD/PI to update the application sections and adjust the budget as appropriate to remove all [insert appropriate activity] activities and submit these updates to the Program Official and Grants Management Specialist for review and approval.
- **Action 2:** Once the IC and the applicant/recipient have reached an agreement, issue the award and include the following Term and Condition of Award in Section IV of the Notice of Award. Hard funds restrictions are not required.

Term of Award (Approved 2/28/2025 – Refer to Appendix 4 for the approval from Dr. Memoli):

NIH and the recipient have renegotiated the scope of this award. Pursuant to the revised scope, NIH funds may only be used to support activities within the revised scope of the award. NIH funds may not be used to support activities that are outside the revised scope of the award, including [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of concern, e.g., China or South Africa, etc.] research or related research training activities or programs. Any funds used to support activities outside the scope will result in a disallowance of costs, and funds will be recovered.

This term is consistent with NIH's ongoing internal review of NIH's priorities and the alignment of awards with those priorities as well as a review of program integrity of awards. Such review includes, but is not limited to, a review for fraud, waste and abuse, and a review of the NIH portfolio to determine whether awards are in the best interests of the government and consistent with policy priorities. If recipients are unclear on whether a specific activity constitutes [select one of the following: diversity, equity and inclusion (DEI) research programs, gender identity, vaccine hesitancy, climate change or countries of

contacting, e.g., the South African Ambassador for her question regarding other activities that could be considered outside the scope of the award, refrain from drawing down funds and consult with the funding IC, particularly where the activity may impact the specific aims, goals, and objectives of the project.

- **Unable to remove activities that are not an NIH/HHS priority/authority:** If the IC and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the IC cannot proceed with the award. For ongoing projects, the IC must work with OPERA to negotiate a bilateral termination of the project. Where bilateral termination cannot be reached, the IC must unilaterally terminate the project. Terminated awards (bilaterally or unilaterally) should follow the process identified in Category 4.
- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICs must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the DEI Term and Condition of Award in Section IV of the NOA of the parent grant. The IC must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the IC must revise the prior year award to remove references to those outyear commitments.
- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific topics that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the IC must work with the applicant/recipient to open the conference up to all populations. If a negotiation to broaden the target audience is not feasible, or the conference is no longer viable, then the IC must terminate the award following the process in Category 4.
- **Diversity Reports (e.g., Ts, R25, K12, and any others):** NIH is modifying the application instructions and RPPR instructions to remove requirements for diversity reports (e.g., Trainee Diversity Report). If ICs receive these reports in applications or RPPRs, the IC should not review the report. These reports provide diversity related information, but do not involve specific DEI activities. ICs must use the following term: "NIH no longer requires the [name of diversity table/plans]. Therefore, NIH did not review the [name of diversity table/plans] provided. NIH funding may not be used to support any diversity, equity or inclusion (DEI) activities". Note: this section applies to diversity related reports, only. Other areas that are no longer NIH/HHS priorities/authority

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Prospective reviews by GM where the DEI language in certain sections of the application has to be removed even though the project itself is not focused on DEI but may have language or have been awarded from a DEI NOFO that is expired/taken down for revision to go back up once the language is appropriately excised.

Examples below, and in these cases, IC should consider using the Category 2 term of award but remove the negotiation language from the term:

- Resource Section
- Biosketch
- RPPRs

Category 2C:

Subprojects terminated by HHS.

- OPERA will restrict the funds associated with the project. No action required from the IC.

Category 3: Project does not support any DEI activities

- Action: IC may proceed with issuing the award.

Category 4/HHS Departmental Authority Terminations:

- OPERA receives a list from the Director, NIH or designee.
- OPERA will issue termination letters on behalf of the IC Chief Grants Management Officers. The IC CGMO will be copied on the email with the termination letter.
  - **Supplements – Parent Award Terminated:** If a terminated award has active supplement(s), all supplement awards must be terminated along with the parent.
  - **Supplement Terminated Only**: If a termination letter references a supplement only, and not the parent award, then the supplement alone must be terminated following the instructions below.
  - **Linked (or equivalent) Awards**: If one linked (or equivalent) award is terminated, the IC is only required to terminate the specific award noted in the letter. The IC must conduct a separate review to determine whether terminating that award will have a structural impact on the scientific design along with associated outcomes and act, as appropriate, to early terminate or allow the remaining awards to continue. Feel free to discuss with OPERA, as needed.
- When a termination letter is received, the IC must:
  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final

FFRs are submitted. There is no deobligation action required from the ICs.

- Remove all future years from the project, where applicable. If the grant is in a no cost extension, and HHS requests a termination, the project must be terminated even in a no cost extension. If the grant is in a no cost extension, and HHS did not request a termination, follow the NCE guidance above.
- Include the following Termination Term in the revised NOA:

  It is the policy of NIH not to prioritize [insert termination category language from Appendix 3, verbatim]. Therefore, this project is terminated. [RECIPIENT NAME] may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

  NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

- Note: Appeals language must be included **prior to** October 1, 2025. After October 1, 2025, when HHS will fully adopt 2 CFR 200, per 2 CFR 200.340, termination actions taken based on agency priorities are not appealable. This is different from terminations based on noncompliance (administrative and programmatic).

- eRA provides OPERA with daily reports on NOAs issued, so ICs do not need to report to OPERA on each action completed.

Category 5: Awards to Entities in certain foreign countries

- Additional guidance on awards to foreign entities is forthcoming. At this time, ICs should hold all awards to entities located in South Africa or countries identified on any of the following lists.
  - State Department Countries of Particular Concern
  - State Sponsors of Terrorism
  - Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern
  - Office of Foreign Assets Control Sanctions List

EXHIBIT 11

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

APRIL 2024

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. These terms and conditions apply not only to the recipients of NIH Grant Awards, but also flow down to any subawards as well as to subrecipients unless specified otherwise in the regulation or the terms and conditions of the specific NIH award (see "Consortium Agreements" on page IIB-114).

This document also is designed to be useful to those interested in NIH grants by providing information about NIH, its organization, its staff and its grants process. The NIHGPS is available online. This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- ***Part I: NIH Grants General Information.*** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- ***Part II: Terms and Conditions of NIH Grant Awards.*** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.
- ***Part III: Points of Contact.*** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term “grant” is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term “recipient” generally is used to refer to recipients of grants and cooperative agreements. “NIH” may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to “Part II (IIA or IIB)” or “Part III” without further elaboration means the corresponding part of the NIHGPS.

SUPERSESSION

The NIHGPS was originally published with an effective date of October 1, 1998. It was subsequently revised several years thereafter with the turn of each new fiscal year (October). This revision of the NIHGPS is an update of the December, 2022 publication. It applies to all NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2023. This version incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the GPS from December, 2022. An explanation of the major changes to the NIHGPS since the previous edition is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIHGPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the *NIH Guide for Grants and Contracts* for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at http://-grants.nih.gov/grants/guide/listserv.htm.

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PART I: NIH GRANTS—GENERAL INFORMATION

This part contains a glossary defining terms and abbreviations commonly used throughout the NIHGPS; describes NIH and its relationship to other organizations within HHS; specifies recipient, NIH, and other HHS staff responsibilities; and outlines the grant application and review processes.

1 GLOSSARY

The glossary lists acronyms and other abbreviations used in the NIHGPS. The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found throughout this document and in source documents, such as applicable statutes and grants administration regulations. This is the only location in the NIHGPS where these terms are defined. If an abbreviation used in the NIHGPS is unfamiliar, the reader should consult this list for its meaning.

1.1 ABBREVIATIONS

Exhibit 1: Abbreviation and full language of acronyms used in the Grants Policy Statement

Abbreviation	Full Meaning of Abbreviation
A&R	Alteration and Renovation
ACF	Administration for Children and Families
ACH	Automated Clearinghouse
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AIA	American Institute of Architects
AoA	Administration on Aging
AOR	Authorized Organization Representative
APAC	Annual Payback Activities Certification
AREA	Academic Research and Enhancement Award
ASHRAE	American Society of Heating, Refrigeration and Air Conditioning Engineers
BSO	Biological Safety Officer
CAS	Cost Allocation Services
CDA	Career Development Award
CDC	Centers for Disease Control and Prevention
CF	Common Form (previously known as Standard Form)
CFR	Code of Federal Regulations

Abbreviation	Full Meaning of Abbreviation
CGMO	Chief Grants Management Officer
CM	Construction Manager
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Confidentiality
COR	Career Opportunities in Research Education and Training Program
CSR	Center for Scientific Review
DAB	Departmental Appeals Board
DCGP	Division of Central Grants Processing, OER, NIH
DCIS	Departmental Contracts Information System
DEA	Drug Enforcement Administration
DEITR	Division of Extramural Inventions & Technology Resources, OPERA, OER, NIH
DES	Department of Engineering Services, NIH
DFAS	Division of Financial Advisory Services, NIH
DGCO	Division of Grants Compliance and Oversight, OPERA, OER, NIH
DGP	Division of Grants Policy, OPERA, OER, NIH
DGSI	Divsion of Grants System Integration, OPERA, OER, NIH
DNA	Deoxyribonucleic acid
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPI	Division of Program Integrity, OMA, NIH
DRR	Division of Receipt and Referral, CSR
DSMB	Data and Safety Monitoring Board
EA	Environmental Assessment
FFR	Federal Financial Report
EIN	Entity Identification Number
EIS	Environmental Impact Statement
EO	Executive Order
eRA	Electronic Research Administration
ESI	Early Stage Investigator

Abbreviation	Full Meaning of Abbreviation
eSNAP	Electronic Streamlined Non-competing Award Process
F&A	Facilities and Administrative (costs)
FAC	Federal Audit Clearinghouse
FAIN	Federal Award Identification Number
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDP	Federal Demonstration Partnership
FEMA	Federal Emergency Management Agency
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report (SF425)
FIC	Fogarty International Center
FICA	Federal Insurance Contributions Act
FOI	Freedom of Information
FOIA	Freedom of Information Act
FTR	Federal Travel Regulation
FWA	Federalwide Assurance
GAAP	Generally Accepted Accounting Principles
GAGAS	Generally Accepted Government Accounting Standards
GeMCRIS	Genetic Modification Clinical Research Information System
GMO	Grants Management Officer
GMP	Guaranteed Maximum Price
GMS	Grants Management Specialist
GPO	Government Printing Office
GSA	General Services Administration
GWAS	Genome-wide Association Studies
hESC	Human Embryonic Stem Cells
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act

Abbreviation	Full Meaning of Abbreviation
HPSL	Health Professional Student Loan
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IBS	Institutional Base Salary
IC	Institute or Center
IDE	Investigational Device Exception
IHE	Institutions of Higher Education
IHS	Indian Health Service
IND	Investigational New Drug
IPA	Intergovernmental Personnel Act
IPF	Institutional Profile File
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRG	Integrated Review Group
IRS	Internal Revenue Service
IVF	In vitro Fertilization
K award	Career Award
Kirschstein-NRSA	Ruth L. Kirschstein National Research Service Award
LWOP	Leave Without Pay
MARC-U*STAR	Maximizing Access to Research Careers Undergraduate Student Training in Academic Research Program
MOU	Memorandum of Understanding
MTDC	Modified Total Direct Cost
NCATS	National Center for Advancing Translational Sciences
NCT	National Clinical Trial
ND	Not Discussed
NEARC	National External Audit Review Center, OIG
NEI	National Eye Institute

Abbreviation	Full Meaning of Abbreviation
NEPA	National Environmental Policy Act
NFI	Notice of Federal Interest
NFPA	National Fire Protection Association
NHSC	National Health Service Corps
NICHD	*Eunice Kennedy Shriver* National Institute for Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH MSID	NIH manuscript submission reference number
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
NINR	National Institute on Nursing Research
NLM	National Library of Medicine
NoA	Notice of Award
NOFO	Notice of Funding Opportunity
NTIS	National Technical Information Service
OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights, HHS
OER	Office of Extramural Research, NIH
OFCCP	Office of Federal Contract Compliance Programs, DoL
OFM	Office of Financial Management, NIH
OHRP	Office for Human Research Protections, HHS
OIG	Office of the Inspector General
OIR	Office of Intramural Research, NIH
OLAW	Office of Laboratory Animal Welfare, NIH
OMA	Office of Management Assessment, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPERA	Office of Policy for Extramural Research Administration, OER, NIH
ORI	Office of Research Integrity, HHS

Abbreviation	Full Meaning of Abbreviation
OSC	Other Significant Contributor
P.L.	Public Law
PA	Program Announcement
PAR	Program Announcement with Special Review Criteria and/or Special Receipt Dates
PD/PI	Program Director/Principal Investigator
pdf	portable document format
PHS	Public Health Service
PII	Personally Identifiable Information
PMC	PubMed Central
PMCID	PubMed Central Identification/reference number
PMS	Payment Management System, Payment Management Service, HHS
PO	Program Official
PSC	Payback Service Center, NIH, or Program Support Center, HHS
PTE	Pass-through Entity
R&D	Research and Development
R&R	Research and Related
RePORT	Research Portfolio Online Reporting Tool
RFA	Request for Applications
RFP	Request for Proposals
ROTC	Reserve Officer Training Corps
RPPR	Research Performance Progress Report
S&W	Salaries and Wages
SAM	System for Award Management
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Small Business Administration
SBC	Small Business Concern
SBIR	Small Business Innovation Research Program
SEP	Special Emphasis Panel
SEVIS	Student and Exchange Visitor Information System
SF	Standard Form

Abbreviation	Full Meaning of Abbreviation
SF424(R&R)	Standard Form 424 for Research and Research-Related (R&R)
SII	Successor-In-Interest
SNAP	Streamlined Non-competing Award Process
SO	Signing Official
SPOC	State Single Point of Contact
SRG	Scientific Review Group
SRO	Scientific Review Officer
STTR	Small Business Technology Transfer Program
TVPA	Trafficking Victims Protection Act
U.S.	United States
U.S.C.	United States Code
USCIS	United States Citizenship and Immigration Services
USDA	United States Department of Agriculture
USPS	United States Postal Service
VA	Department of Veterans Affairs
VAMC	VA Medical Center
VANPC	VA-Affiliated Non-Profit research Corporation
VAT	Value Added Tax
VHA	Veterans Health Administration
WIC	Women, Infants and Children

1.2 DEFINITION OF TERMS

Exhibit 2: Definitions of terms used in the Grants Policy Statement

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.
Activity code	A 3-character code used to identify a specific category of extramural research activity, applied to financial assistance mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the Activity Code Search Results webpage.
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Administrative supplement	A request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project.
Advance payment	A payment that a Federal awarding agency or pass through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Allocation	The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives. For additional information, see Cost Considerations—The Cost Principles.

Term	Definition
Allowable cost	A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute). For additional information on each, see Cost Considerations—The Cost Principles.
Alteration and renovation	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major or minor is made by the NIH Program Official. See definition for Modernization.
Applicable clinical trial	Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA.
Animal Welfare Assurance	The Animal Welfare Assurance is part of the required documentation to receive an award for organizations involved in live, vertebrate animal activity conducted or supported by the Public Health Service (PHS). The Animal Welfare Assurance enumerates the organization's commitment to compliance with the PHS Policy on Humane Care and Use of Laboratory Animals and other incorporated laws and policies.
Applicable credit	Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses, insurance refunds; and adjustments of overpayments or erroneous charges.
Application	A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See Application Information and Processes for detailed information about the application process, including an explanation of the types of applications).
Application type code	A single-digit code identifying the type of application received and processed. Application type codes include the following: 1=New; 2=Renewal; 3=Revision; 4=Extension; 5=Non-Competing Continuation; 6=Change of Organization Status (Successor-In-Interest); 7=Change of Recipient or Training Institution; 8=Change of Institute or Division (Type 5 transfer to another NIH IC); 9=Change of Institute or Division (Type 2 transfer to another NIH IC).
Appropriation Act	The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes.

Term	Definition
Assistance listing number	A unique number assigned to identify a Federal Assistance Listing, formerly known as the CFDA number.
Assistance listing program title	The title that corresponds to the Federal Assistance Listings Number. Formerly known as the CFDA program title.
Assurance	A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant.
Audit finding	Deficiencies which an auditor is required by 2 CFR Part 200.516(a) and to report in the schedule of findings and questioned costs.
Audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (that is, questioned costs).
Authorized organization representative	The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Awarding IC	NIH IC responsible for the award, administration, and monitoring of grant supported activities.
Budget	The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass through entity. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
Budget period	The time interval from the start date of a funded portion of an award to the end date of that funded portion (usually 12 months) during which recipients are authorized to expend the funds awarded, including any funds carried forward or other revisions. NIH award project periods (periods of performance) are typically divided by budget periods for budgetary and funding purposes. See Project Period. See Period of Performance.

Term	Definition
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).
Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life. (See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures).
Carryover	Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.
Change in scope	An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the recipient after award. GMO prior approval is required for a change in scope to be allowable under an award. See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Change of Scope for additional information.
Change of PD/PI	A process, usually initiated by the recipient, whereby the federally approved PD/PI is replaced by another individual, with the approval of the GMO.
Change of recipient organization	Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Chief Grants Management Officer	The Grants Management Officer within an awarding agency who is the principal Grants Officer in the Institute or Center. The Chief Grants Management Officer provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each IC has a CGMO.
Claim	Depending on the context, either: (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right: (i) The payment of money in a sum certain; (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or (iii) Other relief arising under or relating to a Federal award. (2) A request for payment that is not in dispute when submitted.

Term	Definition
Clinical research	Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research Studies falling under 45 CFR Part 46.101(b)(4) (the “Common Rule” prior to July 19, 2018 and 45 CFR Part 46.104(d) 4) (the “Revised Common Rule” effective July 19, 2018, Exemption 4) are not considered clinical research by this definition.

Term	Definition
Clinical trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. • See 45 CFR Part 46, Subpart A, referred to as the “Revised Common Rule" definition of research at 45 CFR Part 46.102(l). Pre-2018, see 45 CFR Part 46, Subpart A, referred to as the “Common Rule” definition of research at 45 CFR Part 46.102(d) • See Revised Common Rule definition of human subject at 45 CFR Part 46.102(e)(1). See Common Rule definition of human subject at 45 CFR Part 46.102(f) • The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignm ent of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. • An *intervention* is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and treatment, prevention, and diagnostic strategies. • A *health-related biomedical or behavioral outcome* is defined as the prespecified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and well-being or quality of life. Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases: Phase I. Tests a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Term	Definition
	Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Closeout	The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actions as described in 2 CFR Part 200.344.
Cluster of programs	A grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. “Other clusters” are as defined by OMB in the compliance supplement or as designated by a state for Federal awards the state provides to its subrecipients that meet the definition of a cluster of programs. When designating an “other cluster,” a state must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with 2 CFR Part 200.332(a). A cluster of programs must be considered as one program for determining major programs, as described in 2 CFR Part 200.518, and, with the exception of R&D as described in 2 CFR Part 200.501(c), whether a program-specific audit may be elected.
Code of Federal Regulations	The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.
Cognizant agency for audit	The Federal agency designated to carry out the responsibilities as described in 2 CFR Part 200.513. The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit may be found at the FAC web site.
Cognizant agency for indirect costs	The Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following: (1) For IHEs: 2 CFR Part 200, Appendix III, C.11. (2) For non-profit organizations: 2 CFR Part 200, Appendix IV, C.2. (3) For state and local governments: 2 CFR Pt 200, Appendix V, F.1. (4) For Indian tribes: 2 CFR Pt 200, Appendix VII, D.1.
Co-Investigator	An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a Co-Investigator, if applicable, does not affect the PD/PI’s roles and responsibilities as specified in the NIHGPS, nor is it a role implying multiple PD/PI.

Term	Definition
Competitive revision	A request for (or the award of) additional funds during a current project period to support new or additional activities which are not identified in the current award that reflect an expansion of the scope of the grant-approved activities. Competitive revisions require peer review.
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Compliance Supplement	Appendix XI to 2 CFR Part 200. See Section 93 for HHS Agency Program Requirements.
Component	For the purposes of applications and progress reports, a component is a distinct, reviewable part of a multi-project application or progress report for which there is a business need to gather detailed information identified in the Notice of Funding Opportunity (NOFO). Components typically include general information (component organization, project period, project title, etc.), performance sites, personnel, and budget. The NOFO defines the construction and naming convention for the application; the funded application defines the construction and naming convention for the progress report. Components may also be referred to as "cores" or "projects." Note, for RPPR Question G.9, the term "foreign component" is distinct from "component" as defined here. However, a "foreign component" may also be a "component" in the RPPR. (See definition of foreign component for more information).
Computing devices	Machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or ''peripherals'') for printing, transmitting and receiving, or storing electronic information. See also "supplies" and "information technology systems."
Conference (domestic or international)	A symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting.
Conference grant	A grant whose purpose is to support activities related to the conduct of a conference(s) or defined set of conference-related activities.
Conflict of interest	Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual's judgment or could cause the individual's impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process. See also Financial Conflict of Interest for a specific definition covering that policy area.

Term	Definition
Consortium agreement	A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB).
Construction	Construction of a new building structure or facility, including the installation of fixed equipment, which provides space not presently available. It excludes the purchase of land and ancillary improvements, for example, parking lots or roads. The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities). See Construction chapter in IIB.
Consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services).
Contact PD/PI	When multiple PD/PIs are designated, NIH requires that the applicant organization identify one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. See Multiple PI chapter in IIB for additional information.
Contract	A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in 2 CFR Part 200 does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward. See Subaward.
Contractor	An entity that receives a contract. See contract.

Term	Definition
Cooperative agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302–6305: (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal government or pass-through entity's direct benefit or use; (2) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. (3) The term does not include: (i) development agreement as defined in 15 U.S.C. 3710a; or (ii) An agreement that provides only: (A) Direct United States Government cash assistance to an individual; (B) A subsidy; (C) A loan; (D) A loan guarantee; or (E) Insurance.
Cost allocation plan	Central service cost allocation plan or public assistance cost allocation plan.
Cost objective	A program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect (Facilities & Administrative (F&A)) cost activity, as described in 2 CFR Part 200, Subpart E—Cost Principles.
Cost overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
Cost principles	The government-wide principles established under 2 CFR Part 200 for determining the allowable costs incurred by non-Federal entities under Federal awards. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of Federal Government participation in the financing of a particular program or project. The principles are designed to provide that Federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute. In the case of hospitals, they follow the cost principles in 2 CFR Part 200, Appendix IX, "Hospital Cost Principles." In the case of for-profit organizations, there are no cost principles specifically applicable; the cost principles for for-profit organizations are set forth in the FAR (48 CFR Part 31.2). See Cost Considerations—The Cost Principles for additional details.
Cost sharing	See matching or cost sharing definition.
Cost sharing or matching alternative	An alternative use of program income whereby income accrued during the period of grant support may be used to satisfy a cost sharing or matching requirement. (See also definitions for additive alternative and deductive alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Cost-type contract	A contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee.

Term	Definition
Data and safety monitoring plan	For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects.
Data Management	The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.
Data Management and Sharing Plan (DMS Plan)	A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.
Data Sharing	The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.
Debarment and suspension	The actions taken by a debarring official in accordance with OMB guidance at 2 CFR Part 180, "Non-procurement Debarment and Suspension," as implemented by HHS in 2 CFR Part 376, to exclude a person or organization from participating in grants and other non-procurement awards government-wide. If debarred or suspended, the person or organization may not receive financial assistance (under a grant, cooperative agreement, or subaward, or contract under a grant) for a specified period of time. Debarments and suspensions carried out pursuant to 2 CFR Part 376 are distinct from post-award suspension action by an awarding agency. (See also Public Policy Requirements and Objectives—Debarment and Suspension).
Debt collection	The process of collecting funds owed by recipients to the Federal government, which, under grants, generally are owed as a result of formal cost disallowances.
Debt instrument	A document used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions.
Deductive alternative	An alternative for the use of program income earned during the period of grant support under which allowable costs of the project or program to be paid by the Federal government are offset by the amount of the program income. (See also definitions for additive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Departmental Grants Appeals Board	The independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR Part 16 and to perform other review, adjudication and mediation services as assigned.

Term	Definition
Deviation	A departure on a single-case or class basis from a regulatory or policy requirement. A single-case deviation represents a request for waiver or exception sought for one grant only that arises on a case-by-case basis. A class deviation involves more than one grant for which the same type of deviation action is being requested.
Direct costs	Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
Disallowed costs	Those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award.
Discretionary Award	An award in which NIH, in keeping with its statutory authority to exercises judgement ("discretion"), selects the recipient and/or the amount of funding through a competitive process. Generally, NIH awards are discretionary. See Non-Discretionary Award.
Domestic organization	A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.
Early Stage Investigator	An individual who is classified as a New Investigator and is within 10 years of completing their terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). See definition of New Investigator.
Entity Identification Number	A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next nine characters are the Employer Identification Number. The last two characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one. (Also known as Payment System Identifier.)
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (See also capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies).
eRA Commons	The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural recipient organizations, recipients, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively.

Term	Definition
Expanded authorities	A standard term of all NIH awards to allow recipients several flexibilities to waive the requirement for prior approval for specified actions. NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances for certain awards. (see Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award).
Expenditure report	Means: (1) For non-construction grants, the SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report); (2) for construction grants, the SF-271 "Outlay Report and Request for Reimbursement" (or other OMB-approved equivalent report)
Expenditures	Charges made by a non-Federal entity to a project or program for which a Federal award was received. 1. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. 2. For reports prepared on a cash basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense charged; iii. The value of third-party in-kind contributions applied; and iv. The amount of cash advance payments and payments made to subrecipients. 3. For reports prepared on an accrual basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense incurred; iii. The value of third-party in-kind contributions applied; and iv. The net increase or decrease in the amounts owed by the non-Federal entity for: A. Goods and other property received; B. Services performed by employees, contractors, sub-recipients, and other payees; and C. Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.
Facilities and Administrative (F&A) costs (or indirect costs)	Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.
Federal agency	An ‘‘agency’’ as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552 (f).

Term	Definition
Federal Audit Clearinghouse (FAC)	The clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages required by Subpart F—Audit Requirements of 2 CFR Part 200 Subpart F – Audit Requirements. The mailing address of the FAC is Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132. Any future updates to the location of the FAC may be found at the Federal Audit Clearinghouse web site.
Federal award	Depending on the context, in either paragraph (1) or (2) of this section: (1)(i) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101; or (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101. (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of Federal financial assistance, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations. (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs). (4) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.
Federal award date	The date when the Federal award is signed by the authorized official of the Federal awarding agency.
Federal Award Identification Number	A unique number assigned to a financial assistance award to assist recipients in correctly reporting subawards. The public can use the FAIN and the Assistance listing number together to find one accurate result when searching online in such databases as USASpending.gov and FSRS. The FAIN can be found on the notice of award. NIH implements the FAIN by deriving it from the core elements of the grant number. For example, the FAIN for 1R0lHL654321-01 would be R01HL654321.
Federal awarding agency	The Federal agency that provides a Federal award directly to another entity. See also Awarding IC.
Federal Demonstration Partnership	A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.

Term	Definition
Federal financial assistance	1. Federal financial assistance means assistance that non-Federal entities receive or administer in the form of: i. Grants; ii. Cooperative agreements; iii. Non-cash contributions or donations of property (including donated surplus property); iv. Direct appropriations; v. Food commodities; and vi. Other financial assistance (except assistance listed in paragraph (b) of this section). 2. For 2 CFR Part 200.202 and 2 CFR Part 200 Subpart F, federal financial assistance also includes assistance that non-Federal entities receive or administer in the form of: i. Loans; ii. Loan Guarantees; iii. Interest subsidies; and iv. Insurance. 3. Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in 2 CFR Part 200.502(h) and (i).
Federal institution	A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. For the purposes of this document, this term is used in the context of a Federal institution as a recipient. See also Awarding IC.
Federal interest	For purposes 2 CFR Part 200.330 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the: (1) Federal share of total project costs; and (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.
Federal program	1. All Federal awards which are assigned a single number in the Assistance listings. 2. When no Assistance listing number is assigned, all Federal awards to non- Federal entities from the same agency made for the same purpose should be combined and considered one program. 3. Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are: i. Research and development (R&D); ii. Student financial aid (SFA); and iii. ‘‘Other clusters,’’ as described in the definition of Cluster of Programs.

Term	Definition
Federal share	The portion of the total project costs that are paid by Federal funds.
Federalwide Assurance	The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in nonexempt research involving human subjects conducted or supported by HHS. Under a FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR Part 46, as well as the terms of assurance.
Fee	An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as profit. (See Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee).
Financial conflict of interest	A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives—Financial Conflict of Interest.
Foreign component	The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: • collaborations with investigators at a foreign site anticipated to result in co-authorship; • use of facilities or instrumentation at a foreign site; or • receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components chapter in IIB).

Term	Definition
Foreign organization	An entity that is: 1. A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance; 2. A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public; 3. A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or 4. An organization located in a country other than the United States not recognized as a *Foreign Public Entity*.
Foreign public entity	(1) A foreign government or foreign governmental entity; (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f); (3) An entity owned (in whole or in part) or controlled by a foreign government; or (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.
For-profit organization	An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. A for-profit organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. (Also see definition for small business concern).
Full-time appointment	The number of days per week and/or months per year representing full-time effort at the applicant/recipient organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. See also "Equipment" and "Special Purpose Equipment."
Generally Acceptable Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).

Term	Definition
Generally Accepted Government Auditing Standards (GAGAS)	Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Grant number	A grant number is a unique identifier for a grant composed of the application type code, activity code, Institute code, 6-digit serial number, support year and /or suffix code for the support year of the grant, or other information, such as a supplement (S1), resubmission (A1), or a fellowship's institutional allowance. In Federalwide systems (e.g., USASpending.gov, FFATA/FSRS) the Federal Award Identifier Number (FAIN) is used to identify grants for Federalwide implications. Similar to the NIH Grant Number, the FAIN consists of the activity code, Institute code, and 6-digit serial number. Sample Grant Number: 1 R01 AI 123456-01 A1 S1 Sample FAIN: R01 AI 654321
Grant or grant agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304: 1. Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or passthrough entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or pass-through entity's direct benefit or use; 2. Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the Federal awarding agency or passthrough entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. 3. Does not include an agreement that provides only: i. Direct United States Government cash assistance to an individual; ii. A subsidy; iii. A loan; iv. A loan guarantee; or v. Insurance. See also Cooperative Agreement.

Term	Definition
Grants Management Officer	An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the CGMO to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards. See also Chief Grants Management Officer definition.
Grants Management Specialist	An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to recipients; and administering grants after award.
Grants.gov	Grants.gov has been designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities.
Grant-supported project or activity	Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.
Honoraria	Payments given in support of professional services for the purpose of conferring distinction or to symbolize respect, esteem, or admiration. In other words, if the service is related to research oversight, research supervision, co-authoring research papers, then the payments are not honoraria but considered research funding.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Human Fetal Tissue	Human Fetal Tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as NIH guidance. See also Human Fetal Tissue from Elective Abortion.

Term	Definition
Human subject	Revised Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Pre-2018 Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Data through intervention or interaction with the individual; or (ii) Identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives—Human Subjects Protections).
Impact score	The impact score is the rating which is assigned to an individual application by an SRG and designates the reviewers' assessment of scientific and technical merit of the application. For research projects, this is defined as the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact scores may be numeric (10 – 90) or alphabetical (ND, for example).
Improper payment	(1) Any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and (2) Includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper.

Term	Definition
Indian tribe (or "federally recognized Indian tribe")	Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.
Indirect costs	See facilities and administrative costs definition.
Information technology systems	Computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. See also computing devices and equipment.
Innovation	Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of innovation would be new medical or biological products for improved value, efficiency, or costs.
Institute or Center	The NIH organizational component responsible for a particular grant program or set of activities. The terms "NIH IC," or "awarding IC" are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award.
Institutional Animal Care and Use Committee	The *PHS Policy on Humane Care and Use of Laboratory Animals* incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
Institutional base salary	The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/recipient organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages).
Institutional Review Board (IRB)	An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

Term	Definition
Institutions of Higher Education (IHEs)	IHE is defined at 20 U.S.C. 1001.
Intangible property	Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).
Intergovernmental Personnel Act (IPA)	The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribe (or "federally recognized Indian tribe" governments, federally funded research and development centers, and other eligible organizations. The goal of the Intergovernmental Personnel Act mobility program is to facilitate the movement of employees, for short periods of time, when this movement serves a sound public purpose.
Internal control over compliance requirements for Federal awards	A process implemented by a non-Federal entity designed to provide reasonable assurance regarding the achievement of the following objectives for Federal award: 1. Transactions are properly recorded and accounted for, in order to: i. Permit the preparation of reliable financial statements and Federal reports; ii. Maintain accountability over assets; and iii. Demonstrate compliance with Federal statutes, regulations, and the terms and conditions of the Federal award; 2. Transactions are executed in compliance with: i. Federal statutes, regulations, and the terms and conditions of the Federal award that could have a direct and material effect on a Federal program; and ii. Any other Federal statutes and regulations that are identified in the Compliance Supplement; and 3. Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition.
Internal controls	A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations.
International organization	An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.

Term	Definition
Invention reporting	The requirement pursuant to 37 CFR Part 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights.
Investigational new drug	A new drug or biological drug that is used in a clinical investigation.
Investigator-initiated research	Research funded as a result of an investigator, on their own, submitting a research application in response to Parent Announcements only. Also known as unsolicited research.
IPF number	Institutional Profile File (IPF) number is a unique number used by NIH for tracking/reporting awards to recipient institutions.
Just-in-Time	NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding. Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by NIH. Through this module, institutions can electronically submit the information that is requested after the review, but before award. See Completing the Pre-Award Process—Just-In-Time Procedures for additional information.
Liquidated damages	An amount defined in a contract and chargeable against funds due to the contractor for each day the contractor fails to complete the project beyond the contract completion date.
Local government	Any unit of government within a state, including a: (1) County; (2) Borough; (3) Municipality; (4) City; (5) Town; (6) Township; (7) Parish; (8) Local public authority, including any public housing agency under the United States Housing Act of 1937; (9) Special district; (10) School district; (11) Intrastate district; (12) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (13) Any other agency or instrumentality of a multi-, regional, or intra-state or local government.
Major A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. See "Modernization" on page I-32.
Matching or cost sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third-party in-kind contributions, as well as expenditures by the recipient.
Mechanism	Extramural awards are divided into three types of financial assistance: *grants*, *cooperative agreements* and *contracts*. A mechanism is the type of funded application or transaction used by NIH. Within each mechanism NIH includes programs. Programs can be further refined by specific activity codes.

Term	Definition
Merger	A legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for the recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change will apply.
Metadata	Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).
Micro-purchase	A purchase of supplies or services using simplified acquisition procedures, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchases comprise a subset of a non-Federal entity's small purchases. Micro-purchase threshold means the dollar amount at or below which a non-Federal entity may purchase property or services using micro-purchase procedures (see § 2 CFR Part 200.320). Generally, the micro-purchase threshold for procurement activities administered under Federal awards is not to exceed the amount set by the FAR at 48 CFR Part 2, Subpart 2.1, unless a higher threshold is requested by the non- Federal entity and approved by the cognizant agency for indirect costs (For NIH DCA for non-profits or DFAS for for-profit organizations).
Minor A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. See "Modernization" on the next page. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as F&A costs.

Term	Definition
Modernization	Modernization. Alteration, renovation, remodeling, improvement, expansion or repair of, or completion of shell space in an existing building (whether for storage or for human occupancy), necessary to make the building suitable for use for the purposes of a particular program. Modernization is distinct from construction in that it leaves the existing structure in place. This can range from updating flooring to replacing everything except for the existing mainframe and foundations. When the primary purpose of the award is to modernize biomedical research facilities, the grant cannot support the conduct of any research. Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. Examples of activities of Major A&R are as follows: • A structural change (e.g., to the foundation, roof, floor or exterior load-bearing walls of a facility, or extension of an existing facility) to increase the floor area and/or change the function and purpose of a facility Examples of activities of Minor A&R are as follows: • Changes to physical characteristics (interior dimensions, surfaces, and finishes); internal environments (temperature, humidity, ventilation, and acoustics); or utility services (plumbing, electricity, gas, vacuum, and other laboratory fittings); • Installation of fixed equipment (including casework, fume hoods, large autoclaves, biological safety cabinets); • Replacement, removal, or reconfiguration of interior non-load bearing walls, doors, frames, or windows in order to place equipment in a permanent location; • Making unfinished shell space suitable for purposes other than human occupancy, such as storage of pharmaceuticals; or • Alterations to meet requirements for accessibility by physically disabled individuals.
Modified Total Direct Cost (MTDC)	All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

Term	Definition
Modular application	A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.
Monitoring	A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.
Name change	An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.
New Investigator	A PD/PI who has not previously competed successfully as a PD/PI for a substantial NIH independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains their status as a New Investigator. A complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/#definition. See also the definition of Early Stage Investigator.
No-cost extension	An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements.
Non-competing continuation application/award	A financial assistance request (in the form of an application or progress report) or resulting award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.
Non-Discretionary Award	An award made by NIH to specific recipients in accordance with statutory, eligibility and compliance requirements, in which NIH has no ability to exercise judgement. The award amount could be determined specifically or by formula. NIH does not typically make non-discretionary awards. See "Discretionary Award" on page I-19.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient.
Non-Federal share	When cost sharing or matching is required as a condition of an award, the portion of allowable project/program costs not borne by the Federal government.
Non-profit organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses net proceeds to maintain, improve, or expand the operations of the organization.

Term	Definition
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: 1. notifies the recipient of the award of a grant; 2. contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, 3. provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Notice of Funding Opportunity (NOFO)	A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. NIH Notices of Funding Opportunities may also be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names as described in 2 CFR 200.204,) depending on the Agency and type of program. Notices of Funding Opportunities can be found at grants.gov and in the NIH Guide for Grants and Contracts.
Obligations	When used in connection with a non- Federal entity's utilization of funds under a Federal award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non- Federal entity during the same or a future period.
Office of Management and Budget (OMB)	The Executive Office of the President, Office of Management and Budget.
Offset	IC or awarding agency approval/authorization of the use of unobligated grant funds remaining from a prior budget period to support grant activities of the current budget period. An offset does not change the current budget period authorized amount of funding but does reduce the amount of current fiscal year funds provided to support the authorized award amount.
Open Researcher and Contributor Identifiers (ORCID iDs)	Unique, persistent digital identifiers that distinguish individual investigators and can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. These free identifiers are assigned and maintained by the non-profit organization ORCID.
Organization	A generic term used to refer to an Institution of Higher Education or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.
Other Significant Contributors	Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.

Term	Definition
Other support	Includes all resources made available to researcher or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. Other support does not include training awards, prizes, start-up support from the US based institution, or gifts. (note: Gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return).
Oversight agency for audit	The Federal awarding agency that provides the predominant amount of funding dir-ectly (direct funding) (as listed on the schedule of expenditures of Federal awards, see 2 CFR Part 200.510(b)) to a non-Federal entity unless OMB des-ignates a specific cognizant agency for audit.. When the direct funding rep-resents less than 25 per-cent of the total Federal expenditures (as direct and subawards) by the non-Federal entity, then the Federal agency with the pre-dominant amount of total funding (direct and subawards) is the designated cog-nizant agency. When there is no direct fund-ing, the Federal awarding agency which is the predominant source of pass-through funding must assume the over-sight responsibilities. The duties of the oversight agency for audit and the pro-cess for any reassignments are described in 2 CFR Part 200.513(b).
Parent announcement	Broad NOFO enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01).
Participant support costs	Direct costs for items such as stipends or subsistence allowances, travel allow-ances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects. For the pur-poses of Kirschstein-NRSA programs and Education Grants (e.g., R25), this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travelfor those programs.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program (see 2 CFR 200.1).
Payback	Requirement that the recipient of a NRSA postdoctoral fellowship engage in qual-ified health-related research, health-related research training, or health-related teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis. See Ruth L. Kirschstein National Research Service Awards—Pay-back for additional information.
Payment Management System	The HHS centralized grants payment system operated by the Payment Man-agement Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive grant payments through this system.

Term	Definition
Peer review	The two-stage process that involves the consistent application of standards and procedures that produce fair, equitable, timely, and objective examinations of applications based on an evaluation of scientific or technical merit or other relevant aspects of the application. The review is performed by experts (Peer Reviewers) in the field of endeavor for which support is requested. Peer review is intended to provide guidance and recommendations to the NIH individuals responsible for making award decisions.
Period of performance	The total estimated time interval between the start of an initial Federal award and the planned end date, which may include one or more funded portions, or budget periods. Identification of the period of performance (project period) in the Federal award does not commit the awarding agency to fund the award beyond the currently approved budget period. The period of performance for NIH awards is noted on the Notice of Award. See "Project period" on page I-38 as well as "Budget period" on page I-10.
Person months	The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.
Phase III clinical trial	As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See clinical trial definition).

Term	Definition
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs.
Prior approval	Written approval by an authorized HHS official, e.g., a designated IC GMO, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Profit	See definition for fee.
Program	A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.
Program Director/Principal Investigator	The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the official(s) at the applicant organization/recipient, or as appropriate, to a collaborating organization for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.
Program income	Gross income earned by the non-Federal entity that is directly generated by a sup-ported activity or earned as a result of the Federal award during the period of per-formance except as provided in 2 CFR Part 200.307(f). (See Period of performance.) Program income includes but is not limited to income from fees for services performed, the use or rental or real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See 2 CFR Part 200.307, 45 CFR Part 200.307, 2 CFR Part 200.407 and 35 USC §§ 200-212 for inventions made under Federal awards. (See Administrative Requirements—Management Systems and Procedures—Program Income).
Program Official/Program Officer/Project Officer	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement.

Term	Definition
Progress report	Periodic, usually annual, report submitted by the recipient and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. This report may also be called the non-competing continuation progress report.
Project period	The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions. See "Period of performance" on page I-36. Also see "Budget period" on page I-10.
Project/performance site	Location(s) of where the work described in the research plan will be conducted.
Property	Real property or personal property.
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (See Personally Identifiable Information (PII)).
Questioned cost	A cost that is questioned by the auditor because of an audit finding: 1. Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; 2. Where the costs, at the time of the audit, are not supported by adequate documentation; or 3. Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Recipient	An entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients nor consortiums of the award. See Non-Federal entity.
Renewal application	An application requesting additional funding for a period subsequent to that provided by a current award. Renewal applications compete for funds with all other peer reviewed applications, and must be developed as fully as though the applicant is applying for the first time. The previous NIH term was "competing continuation."

Term	Definition
Renewal award	An award made subsequent to an expiring Federal award for which the start date is contiguous with, or closely follows, the end of the expiring Federal award. A renewal award's start date will begin a distinct period of performance.
Research & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. ‘‘Research’’ is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. ‘‘Development’’ is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Research Administrator	The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. See also Roles and Responsibilities—Recipient Staff.
Research misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. 1. Fabrication is making up data or results and recording or reporting them. 2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. 3. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. 4. Research misconduct does not include honest error or honest differences of opinion.
Research patient care costs	Costs of routine and ancillary services provided by hospitals to participants in research protocols.
Responsible party	Responsible party is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to refer to the entity or individual who is responsible under FDAAA for registering a clinical trial and submitting clinical trial information to ClinicalTrials.gov.
Resubmission application	An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available from review of the first submission. Applicants must apply and undergo peer review. Additional policies on resubmissions can be found in the applicable Application Instruction Guide. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1.

Term	Definition
Revision application	As defined in the Federalwide SF424 (R&R): An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH recipients use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1.
Scientific Data	The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
Scientific Review Group (SRG)	A peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of any SRG may be Federal employees, as noted in 42 CFR Part 52(h).
Scientific Review Officer (SRO)	The NIH official who serves as the designated Federal officer having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest, as noted in 42 CFR Part 52(h).
Scope of work	The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications.
Senior/Key Personnel	The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.

Term	Definition
Significant rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.
Simplified acquisition threshold	The dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1. (See also Micro-purchase.)
Small business concern	A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR Part 121.
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. See also Equipment and General purpose equipment.
State	Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.
State government	The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS.
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.

Term	Definition
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.
Subsidiary	An entity in which more than 50 percent of the entity is owned or controlled directly by a parent corporation or through another subsidiary of a parent corporation.
Successor-in-interest	Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
Supplies	All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or $5,000, regardless of the length of its useful life. See Computing devices and Equipment.
Suspension of award activities	An action by the NIH awarding IC requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR Part 376) implementing Executive Orders 12549 and 12689. (See Public Policy Requirements and Objectives—Debarment and Suspension and Administrative Requirements—Enforcement Actions).
Termination	The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance.
Terms and conditions of award	All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NoA may include both standard and specific award conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non- Federal entity under a Federal award.
Total costs	The total allowable costs (both direct costs and F&A costs) incurred by the recipient to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
Uniform Administrative Requirements ("Uniform Guidance")	The administrative requirements, cost principles and audit requirements for Federal awards to non-Federal entities as set forth in Part 200 of CFR Title 2 (Grants and Agreements), also referred to as "Uniform Guidance".

Term	Definition
Unique Entity Identifier (UEI)	The identifier assigned by the System for Award Management (SAM) to uniquely identify business entities.
United States	The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.
Withholding of support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart A: General

3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

NIH recipients are responsible for complying with all requirements of the Federal award. NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recent legislation.
- 2 CFR Part 200.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 2 CFR Part 200, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted on the National Science Foundation's web site. Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions is also known as the "NIH Standard Terms of Award".

See Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award for more details.

4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES

NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Recipients are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

This chapter addresses public policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term "public policy" indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by recipients, subrecipients, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities.

In addition to cross-cutting requirements that some or all Federal agencies must apply to their grant programs, NIH recipients and subrecipients are subject to requirements contained in the HHS annual appropriations act that apply to the use of NIH grant funds, applicable provisions in other Federal agencies' appropriations acts, including Treasury, and other Federal statutes. Some of those requirements are included here in a separate section titled Appropriation Mandates since they have been included in the appropriations acts for several years with little or no change. Those requirements may be changed or other requirements may be added in the future.

The public policy requirements, objectives, and appropriation mandates listed in Exhibit 4 apply to all NIH awards with exceptions as noted.

4.1 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The public policy requirements specified in this section set many of those standards. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. Requirements / objectives are listed in alphabetical order.

As noted in this section, some requirements may necessitate the submission of a separate document (e.g., human subjects assurance, certification of IRB approval or institutional exemption, civil rights assurance). Applicants and recipients should take particular note of these requirements (for example, see specific sections on Human Subjects Protections and Civil Rights Protections), the absence or inadequacy of which may delay an award or render an applicant ineligible for award.

The recipient is responsible for: 1) establishing and maintaining the necessary processes to monitor its compliance and that of its employees, consortium participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

If a grant is awarded on the basis of false or misrepresented information, or if a recipient does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in Administrative Requirements—Enforcement Actions or other available legal remedies.

Exhibit 4 contains information to help the recipient determine what public policy requirements, objectives and appropriations mandates apply to its activities and whether a requirement should be included in a consortium agreement or a contract for routine goods or services under the grant (see Glossary in Part I for definitions). The exhibit distinguishes between these types of transactions under a grant and indicates (by "Y" for Yes or "NA" for Not Applicable) whether a given requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that requirement potentially could be applicable in a specific situation, e.g., if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The recipient should consult the terms and conditions of its award and should contact the GMO if it has any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 4 also indicates where, in the NIHGPS, the individual public policy requirements, objectives and appropriation mandates are covered in more detail. The recipient should also consult its attorney, as appropriate, regarding particular questions about the governing statute or regulation as applied to its specific circumstances. Other cited policies or documents may provide additional information.

In addition to the requirements addressed in this section, there are applicable NIH administrative requirements outlined in the Administrative Requirements chapter.

Some programs may have special requirements and are covered in IIB.

Exhibit 4. Public Policy Requirements, Objectives and Appropriation Mandates *

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Military Recruiting and ROTC Program Access to Institutions of Higher Education 4.1.19	Y	N	N
Seat Belt Use 4.1.28	Y	NA	NA
Labor Standards under Federally Assisted Construction 10.5.3	Y (Construction Grants and major A&R Contracts Exceeding $100,000)	NA	Y
Smoke-Free Workplace 4.1.29	Y	NA	NA
Drug-Free Workplace 4.1.7	Y	NA	NA

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Flood Disaster Protection Act of 1973 –- Flood Insurance 10.10.1	Y (Construction grants only)	NA	NA
National Environmental Policy Act of 1969 (including Public Disclosure) 4.1.20 and 10.10.1	Y	NA	NA
Intergovernmental Review of Federal Programs under EO 12372 10.10.1	Y (Construction grants only)	NA	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 10.10.1	Y	NA	NA
Standards of Conduct 4.1.30	Y	NA	NA
Federal Funding Accountability and Transparency Act (FFATA) 4.1.8 and 8.4.1.5.5	Y	NA If under $30,000	NA If under $30,000
President's Emergency Plan for AIDS Relief (PEPFAR Program 4.1.22	Y	Y	Y
Nondelinquency on Federal Debt 4.1.21	Y	Y	NA
National Historic Preservation Act of 1966 — Archaeological and Historic Preservation Act of 1974 10.10.1	Y (Construction Grants; any award involving major or minor A&R, or any work resulting in physical changes to real property)	Y	Y
Lead-Based Paint Poisoning Prevention Act 10.10.1	Y (Construction grants only)	Y	Y
Investigational New Drug Applications/Investigational Device Exceptions 4.1.16	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Inclusion of Women/Minorities as Subjects in Clinical Research 4.1.15.8	Y	Y	NA
Metric System 4.1.18 and 10.10	Y	Y	Y
Lobbying (Appropriation Mandate) 4.2.6	Y	Y	Y
Limited English Proficiency 4.1.2.5	Y	Y	NA
Pro-Children Act of 1994 4.1.23	Y	Y	Y
Safe Drinking Water Act 10.10.1	Y (Construction grants only)	Y	Y
Salary Limitation/Cap (Appropriation Mandate) 4.2.10	Y	Y	NA
Restriction on Distribution of Sterile Needles (Appropriation Mandate) 4.2.9	Y	Y	Y
Select Agents (see Public Health Security & Bioterrorism Preparedness and Response Act) 4.1.24.1.1	Y	Y	Y
USA Patriot Act 4.1.33	Y	Y	Y
U.S. Flag Air Carriers 7.9.1	Y	Y	Y
Text Messaging While Driving 4.1.31	Y	Y	Y
Restriction on Abortions & Exceptions (Appropriation Mandates) 4.2.8 & 4.2.8.1	Y	Y	Y
Wild and Scenic Rivers Act of 1968 10.10.1	Y (Construction grants only)	Y	Y
Protection of Wetlands (EO 11990) 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Promotion or Legalization of Controlled Substances (Appropriation Mandate) 4.2.7	Y	Y	Y
Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents) 4.1.24.1.1	Y	Y	Y
Research Misconduct 4.1.27	Y	Y	NA
Research Involving Recombinant or Synthetic Nucleic Acid Molecules 4.1.26	Y	Y	Y
Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees 4.1.25	Y	Y	NA
Inclusion of Individuals Across the Lifespan as Participants in Research 4.1.15.7	Y	Y	NA
Copeland Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Controlled Substances 4.1.5	Y	Y	Y
Conservation of Petroleum and Natural Gas (EO 12185) 10.10.1	Y (Construction grants only)	Y	Y
Data and Safety Monitoring 4.1.15.6	Y	Y	Y
Dual Use Research of Concern 4.1.24.2	Y	Y	Y
Dissemination of False or Deliberately Misleading Information (Appropriation Mandate) 4.2.3	Y	Y	Y
Davis-Bacon Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2	Y	Y	Y
Architectural Barriers Act of 1968 10.10	Y (Construction grants and any grant involving major A&R)	Y	Y
Animal Welfare 4.1.1	Y	Y	Y
Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1	Y	Y	NA
Certificates of Confidentiality 4.1.4.1	Y	Y	Y
Coastal Zone Management Act of 1972 10.10	Y (Construction grants only)	Y	Y
Clinical Trials.gov 4.1.3	Y	Y	NA
Clean Air and Clean Water Act 10.10.1	Y (Construction grants only); for contracts exceeding $100,000	Y	Y
Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10	Y (Construction grants only)	Y	NA
Human Subjects Protections 4.1.15	Y	Y	Y
Gun Control 4.2.4	Y	Y	Y
Fly America Act 4.1.11	Y	Y	Y
Hotel and Motel Fire Safety Act of 1990 14.6.1	Y (Conference Grants Only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Human Fetal Tissue Research (Including Transplantation Research) 4.1.14	Y	Y	Y
Human Stem Cell Research 4.1.13	Y	Y	Y
Human Embryo Research and Cloning Ban (Appropriation Mandate) 4.2.5	Y	Y	Y
Health and Safety Regulations and Guidelines 4.1.12	Y	Y	Y
Endangered Species Act of 1973 10.10.1	Y (Construction grants only)	Y	Y
Equal Employment Opportunity 10.5	Y (Construction grants and any grant involving major A&R)	Y	NA If under $10,000
Financial Conflict of Interest 4.1.10	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA
Federal Information System Security Management Act 4.1.9	Y	Y	Y
Age Discrimination Act of 1975 4.1.2.4	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Civil Rights Act of 1964 (Title VI) 4.1.2.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Health Insurance Portability and Accountability Act (HIPAA) 4.1.4.3	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Debarment and Suspension 4.1.6	Y (NA to certain foreign organizations)	Y (NA to certain foreign organizations)	Y If contract equals or exceeds $25,000 (NA to certain foreign organizations)
Education Amendments of 1972 (Title IX) 4.1.2.2	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Rehabilitation Act of 1973 (section 504) 4.1.2.3 and 10.10.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Lobbying (Federalwide Certification) 4.1.17	Y (Certification required if total costs expected to exceed $100,000)	Y (Certification required if greater than $100,000 only)	Y (Certification required on contracts greater than $100,000 only)
Trafficking in Persons 4.1.32	Y (Private entities)	Y (Private entities)	NA
Never Contract with the Enemy 4.1.36	Y	Y	Y
Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment 4.1.37	Y	Y	Y

* NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible recipient, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

Please note that the core set of National Policy Requirements for participating Federal research agencies is maintained by the National Science Foundation and is posted on Research Terms and Conditions website.

4.1.1 Animal Welfare Requirements

The *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all organizations involved in PHS-conducted or supported activities involving live vertebrate animals. This requirement includes organizations that are award

recipients and organizations that serve as performance sites where animal activities will be conducted. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the organization's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). Organizations in foreign countries must also comply with the PHS Policy on Humane Care and Use of Laboratory Animals or may provide evidence to the PHS (i.e. NIH) that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met per Section II of the PHS Policy.

The PHS Policy defines "animal" as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals isnot yet known and cannot be described in the application at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the recipient must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application and meet the Assurance and IACUC approval requirements of the PHS Policy.

Noncompeting and competing awards are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

NIH funds may not be used to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance.

No activities with live vertebrate animals may begin and no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All recipient organizations are required to comply, as applicable, with the regulations (9 CFR, Subpart A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review

those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No activities with live vertebrate animals may be conducted and no costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

Organizations where live, vertebrate animal work is performed onsite (i.e., serve as an animal performance site) must have an approved Domestic or Foreign Assurance. If the pass-through entity does not have an approved Domestic or Foreign Assurance and the animal activities will be conducted at an Assured institution named as a performance site, the recipient must obtain an Interinstitutional Assurance from OLAW. Under the Interinstitutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted not more than three years prior to the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with approved Assurances may wish to proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range.

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC. The applicant verifies that there is congruence between the application and the IACUC-approved protocol when it provides the IACUC approval date.

No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval.

4.1.1.3 Consortiums

Under consortium (subaward) agreements in which the recipient collaborates with one or more other organizations, the recipient, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the recipient as specified in the NIHGPS (see Consortium Agreements chapter in IIB). The animal welfare requirements that apply to recipients also apply to consortium participants and subprojects.

The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.

The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).

The list of domestic and foreign organizations with a PHS approved animal welfare assurance is available on OLAW's website. The list of organizations with approved assurances is available at The OLAW web site posts a list of domestic institutions and foreign institutions with approved assurances.

4.1.1.4 Foreign Recipients and Foreign Performance Sites

Foreign recipients that will perform live, vertebrate animal activity onsite must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. This constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the International Guiding Principles for Biomedical Research Involving Animals. IACUC approval is not required of foreign recipients; however, OLAW encourages foreign recipients to use the standards in the *Guide for the Care and Use of Laboratory Animals*.

When the recipient is a domestic institution and animal performance sites are foreign (i.e., domestic grant with a foreign component), the IACUC approval requirement applies. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activities as conducted at the foreign performance site are acceptable to the recipient). The recipient IACUC may accept, as its own, the approval of a foreign organization's animal welfare committee or oversight body;; however, the recipient IACUC remains responsible for the review. Additionally, the foreign animal performance site must obtain an Animal Welfare Assurance for Foreign Institutions as described in the preceding paragraph.

4.1.1.5 Reporting to OLAW

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the Guide for the Care and Use of Laboratory Animals, and any IACUC suspensions.

Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activities. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Instances of serious noncompliance with section IV.F.3. of the PHS Policy, such as those mentioned above, are to be reported to OLAW and the IC supporting the grant award. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the

report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included.

NIH expects recipients to continue to maintain and care for animals during periods when animal activities are conducted in the absence of a valid Animal Welfare Assurance and/or IACUC approval. ICs may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis. Consultation with the IC is encouraged regarding questions concerning allowable costs.

Information about the PHS Policy, Animal Welfare Assurances, and other relevant topics is available on the OLAW website.

4.1.2 Civil Rights Protections

Recipients are required to administer NIH-funded projects in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy, and comply with applicable conscience protections.

Before NIH may make an award to a domestic organization, the AOR must certify, by means of the signature on the application, that the organization has on file with the HHS OCR a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, HHS Form 690, is filed for the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file, it will receive the required form and instructions for completion and submission from the awarding IC. The HHS Form 690 also is available from GrantsInfo@nih.gov or by telephone at 301-435-0714.

Domestic organizations that receive funding from recipients (including consortium participants and contractors under grants) rather than directly from NIH, also are required to file an HHS 690. The applicant/recipient is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS.

4.1.2.1 Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 80.

4.1.2.2 Educational Amendments of 1972

Title IX of the Education Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 86.

4.1.2.3 Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any

program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR Parts 84 and 85.

4.1.2.4 Age Discrimination Act of 1975

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 91.

4.1.2.5 Limited English Proficiency

EO 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of recipients are explained on the Limited English Proficiency (LEP) page of the HHS website..

4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement

4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

For grant applications that request support for the conduct of a clinical trial, the NIH Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health. For basic experimental studies with humans (BESH) NIH continues to expect registration and results reporting, but with the additional flexibility to register and report results on alternative publicly available platforms. This flexibility is only applicable to BESH studies submitted to Notices of Funding Opportunities designated as “basic experimental studies with humans” in the title and is available until September 24. 2023.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded

in whole or in part by NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

The signature of the AOR on the grant application or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient's clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Recipients of NIH funding conducting non-exempt research involving human subjects research subject to the revised Common Rule and conducting a clinical trial as defined in 45 CFR Part 46.102(b) should be aware that for each funded trial, one IRB-approved consent form must be posted on a designated public federal website in accordance with 45 CFR Part 46.116(h). The forms must be posted on a designated public federal website after recruitment closes and no later than 60 days after the last study visit by any subject, as required by the protocol. More information about these requirements is available on Posting Clinical Trial Informed Consent Forms webpage..

- **NIH-funded recipients using an English-language informed consent form to enroll participants may either:**

Submit an IRB-approved English-language informed consent form to ClinicalTrials.gov. Documents that are uploaded to ClinicalTrials.gov should be uploaded in accordance with these instructions. ClinicalTrials.gov does not currently support upload of non-English documents. Or:

Submit an IRB-approved informed consent form to Regulations.gov following the instructions in the paragraph below. NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number and make it available to NIH upon request.

- **NIH-funded recipients using only non-English informed consent forms to enroll participants:**

Submit an IRB-approved informed consent form to Docket ID: HHS-OPHS-2018-0021 on the Regulations.gov website in accordance with guidance issued by the Office for Human Research Protections. NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number and make it available to NIH upon request.

Institutions submitting documents to either ClinicalTrials.gov or Regulations.gov must protect participant privacy in accordance with applicable federal, state, and local laws and regulations (e.g., the HIPAA Privacy Rule, Certificates of Confidentiality) and any applicable terms of their NIH award.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the applicable clinical trial to comply with this policy.

4.1.3.2 Food and Drug Administration Amendments Act (FDAAA)

Applicants and recipients should familiarize themselves with the requirements of 42 U.S.C. 282(j), also known as Sec. 801 of Public Law 110-85 (the FDA Amendments Act of 2007 or FDAAA), as implemented in regulation by 42 CFR Part 11, with respect to registration and results reporting requirements that apply to certain clinical trials. Of particular note is that, in general, results of applicable clinical trials are due not later than 12 months after the primary completion date. If this date occurs after the period of performance has ended, results reporting is still required in accordance with FDAAA and the terms and conditions of grant award.

The signature of the AOR on the grant or progress report form certifies that, for applicable clinical trials funded in whole or part by the award, the responsible party has made all registration and results submissions required by 42 CFR Part 11.

4.1.3.3 Good Cause Extension (GCE) Request Requirements

Section 402(j) of the Public Health Service Act (PHS Act) and the Final Rule for Clinical Trials Registration and Results Information establish requirements and deadlines for the submission of clinical trial results information for Applicable Clinical Trials (ACTs). In general, the standard submission deadline for clinical trials results information is no later than 1 year after the primary completion date. However, in rare instances, a good cause extension (GCE) request may be sought for the following categories of trials:

- ACTs that are subject to the Final Rule (42 CFR 11.42).
- NIH Clinical trials subject to the complementary policy in Section 4.1.3.1.

Therefore, GCE requests must be submitted through the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to (i.e., the day before) the standard submission deadline or granted extended deadline. Late submissions, or requests submitted outside of the PRS, will not be accepted. If NIH determines the request does not constitute “good cause,” the GCE request will be denied. If the request is denied, the responsible party must either (1) submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due, or 30 calendar days after the date that the PRS GCE denial notification was issued by NIH; or (2) submit an appeal.

Special Considerations for NIH Recipients

For NIH-funded and supported clinical trials, recipients should be aware that any GCE request could impact other aspects of the grant award. Therefore, the submission of a “Request for an Extension for Good Cause” does not constitute a prior approval request submission (e.g., No Cost Extension and Carryover).

Each GCE request must include

1. a complete description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request; and
2. an estimated date on which the clinical trial results information will be submitted.

Extension requests will be evaluated on a case-by-case basis using the following general criteria to support a determination of "good cause." These include, but are not limited to:

General Criteria:

1. The circumstances and their leading to the GCE request, including steps the responsible party is taking to mitigate the impact of those circumstances.
2. The extent to which the factors underlying the GCE request are outside of the responsible party's control.
3. 3. What steps will be taken during the requested extension, why they are necessary to mitigate the circumstances leading to the GCE request, and whether the requested submission date is commensurate with the explanation provided in the request.
4. 4. Whether information is internally consistent with relevant data element definitions and is consistent with information provided in other sections of the study record.
5. 5. The number of, and explanations for, previous GCE request(s), and the proposed reporting deadline in previous requests.

General Formatting Criteria and Considerations:

1. The request must be in English.
2. Acronyms and abbreviations should be spelled out, with the acronym or abbreviation provided in parentheses immediately after, at least the first time they are used in the request.
3. The responsible party should not include specific personal health information in the request.

Sufficient detail should be provided, including the steps that will be taken to meet the estimated submission date, a description of mitigating steps to avoid future delay, and any other information needed to address the criteria listed above. Requests that do not provide sufficient information may be denied.

More than one GCE request may be submitted for the same ACT or NIH Clinical Trial after a previous GCE request was granted. When a GCE is granted, the results submission deadline is updated to align with the approved extension. Any subsequent GCE request must be submitted prior to the granted extended deadline.

Appeals

Responsible parties or Recipients, as appropriate, may appeal denied GCE requests or the NIH-identified earlier deadline specified in a granted extension request. An appeal must provide an explanation of the reason(s) why the initial decision to deny the GCE request or grant the GCE request with a shorter deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal. Responsible parties or Recipients, as appropriate, should provide further elaboration of the grounds for the request or highlight factors that justify an extension. The appeal should only address why the initial decision was incorrect; new bases for an extension request should not be presented for the first time in an appeal and will not be considered.

Only one appeal may be submitted for a denied GCE request. The appeal must be submitted via the PRS not later than 30 calendar days after the date that the PRS notification was issued by NIH. NIH will provide an electronic notification to the responsible party or recipient, as appropriate, communicating the determination of whether the appeal is granted or denied.

If the appeal is granted, the responsible party or recipient, as appropriate, has until the extended date specified in the electronic notification to submit clinical trial results information. If NIH denies the appeal of a denied GCE request, the responsible party or recipient, as appropriate, must submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due, or 30 calendar days after the electronic notification denying the appeal was sent by NIH.

The GCE request review and decision notification process can be found on the NIH Good Cause Extension website.

4.1.4 Confidentiality

4.1.4.1 Certificates of Confidentiality

In keeping with Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255, and as enacted December 13, 2016 Certificates of Confidentiality (Certificates) are issued automatically to any NIH funded investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected.

At the time of enactment, all NIH-funded and conducted research that was commenced or ongoing on or after December 13, 2016 was deemed to be issued a Certificate and was therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Per the PHS Act, subsection 301(d)(1), the Certificates protect identifiable, sensitive information collected and all copies, in perpetuity.

Institutions and their investigators are responsible for determining whether research they conduct is subject to the requirement and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.

For the purposes of this Policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR Part 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Recipient Responsibilities

To determine if the requirement applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then the requirement will apply to the research and therefore, in accordance with subsection 301(d) of the Public Health Service Act, the recipient of the Certificate shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

As set forth in NIHGPS Chapter 8.3, recipients conducting NIH supported research applicable to the Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by the Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. In accordance with NIHGPS Chapter 15.2.1, recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by the Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by the Policy.

Information on CoCs is available on the NIH Web site at Grants and Funding's Certificates of Confidentiality (CoC) webpage.

4.1.4.2 Confidentiality of Alcohol and Substance Use Patient Records

Section 543 of the PHS Act, as implemented in 42 CFR Part 2, requires that records of substance abuse patients be kept confidential except under specific circumstances and purposes. These protections differ from those available to patients under HIPAA and are intended to ensure that a patient in a substance or alcohol use program is not made more vulnerable than a similar patient who does not seek treatment. The covered records are any information, written or not, of a patient who has applied for or been given diagnosis or treatment for substance or drug use at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as a substance or drug user in order to determine that individual's eligibility to participate in a program. This includes records of the identity, diagnosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, training, treatment, rehabilitation, or research, which is conducted under an NIH grant. Except as authorized under a court order, no patient record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. The regulations also describe procedures to allow for nonvoluntary disclosure of certain information by persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive substances.

4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act

HHS issued the final version of the "Standards for Privacy of Individually Identifiable Health Information"—the Privacy Rule—on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS.

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and the recipient organization. The OCR web site provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Heath Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR's web site. That web site also includes other educational materials including information specific to grants.

4.1.5 Controlled Substances

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the substances themselves, applicants/recipient must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6441.

4.1.6 Debarment and Suspension

HHS regulations published in 2 CFR Part 376 implement the government-wide debarment and suspension system guidance (2 CFR Part 180) for HHS' non-procurement programs and activities. "Non-

procurement transactions" include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants ("primary covered transactions"), including sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in 2 CFR Part 180.995 and 2 CFR Part 376.995) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in SAM, although checking SAM is not required.

Prior to the drawdown of funds for each grant award, recipients must report to the funding IC if the recipient or any of its principals:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR Part 180.800(a) or had a civil judgment for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR Part 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years or default.

Disclosure of unfavorable information by recipients under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that recipients elect to submit with the disclosed information. However, if it is later determined that a recipient failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may (a) terminate the transaction for material failure to comply with the terms and conditions of the award or (b) pursue any other available remedies, including suspension and debarment.

Recipients must immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover that they (a) failed to disclose information prior to the drawdown of funds or (b) due to changed circumstances the recipient or any of its principals for the grant now meet the reporting criteria.

"Lower tier" transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed $25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in 2 CFR Part 180.980), recipients must verify that the person (as defined in 2 CFR Part 180.985) is not excluded or disqualified. Recipients may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statue, Executive Order, or regulation has been obtained from HHS.

Recipients must require participants at the next lower tier to (a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and (b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods or services that will equal or exceed $25,000) must report to the recipient if it or any participants are presently excluded or disqualified.

Recipients also are required to assure compliance for each trainee under a Kirschstein-NRSA institutional research training grant, or other similar NIH-supported institutional training grant, before their appointment.

Organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period, charges made to NIH grants for such individuals (e.g., salary) are unallowable.

4.1.7 Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOR agrees that the recipient will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR Part 182; HHS implementing regulations are set forth in 2 CFR Part 382.400. All recipients of NIH grant funds must comply with the requirements in Subpart B (or Subpart C if the recipient is an individual) of Part 382. Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR Part 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

4.1.8 Federal Funding Accountability and Transparency Act (FFATA)

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible web site, USASpending.gov. The Web site includes information on each Federal financial assistance award and contract over $30,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including FAIN, transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all subawards/subcontracts/consortiums over $30,000. Information on the recipient reporting requirement for this law can be found in Monitoring—Reporting—Financial Reports—Recipient Reporting of Subrecipient Data for FFATA.

Full text of the award term is available at 2 CFR Part 170.

4.1.9 Federal Information Security Management Act

All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIH recipients applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The recipient retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

4.1.10 Financial Conflict of Interest

NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements. FCOI requirements are aligned with 42 CFR Part 50--Subpart F and the overarching goal for reporting is to promote and encourage transparency in order to avoid distorting NIH funding decisions; NIH staff consider reports in light of other disclosures, e.g. other support, biographical sketch data, and foreign components, etc., and provide a holistic approach to award and risk management principles.

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing FCOI for employees. When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of the FCOI regulations, including that:

1. There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage FCOI with respect to all research projects for which NIH funding is sought or received;
2. The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFI);
3. The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to NIH;
4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
5. The Institution must fully comply with the requirements of the regulation.

When the Institution determines that an FCOI exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- Value of the financial interest $0-4,999; $5,000-9,999; $10,000-19,999; amounts between $20,000-100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan, including:
    1. Role and principal duties of the conflicted Investigator in the research project;
    2. Conditions of the management plan;
    3. How the management plan is designed to safeguard objectivity in the research project;
    4. Confirmation of the Investigator's agreement to the management plan;
    5. How the management plan will be monitored to ensure Investigator compliance; and
    6. Other information as needed.

The annual FCOI report must be submitted to NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the management plan, if applicable

The Institution must enter into a formal written agreement, signed and agreed to by the recipient and each consortium participant and/or subrecipient. The agreement must establish whether the FCOI policy of the recipient Institution or that of the subrecipient will apply to subrecipient Investigators and in either case, the agreement must include required significant financial interest disclosure, review, and FCOI reporting timelines to ensure compliance with the FCOI regulations. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the recipient Institution in sufficient time to allow the recipient Institution to report the FCOI to NIH to meet its reporting obligations. (See Consortium Agreements, 15.2.1 Written Agreement.)

NIH will not support any agreement that does not meet the minimum requirements. If a subrecipient is unwilling to accept the requirements of the written agreement by signing the agreement, then the agreement cannot be issued. NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions (See 8.5, Specific Award Conditions and remedies for noncompliance).

The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible web site or by a written response to any

requestor within five business days of a request and update such information as specified in the regulation.

Each Institution shall maintain an up-to-date, written, enforced policy on FCOI that complies with the regulation, and make the policy available via a publicly accessible web site. NIH funded recipients are required to submit their publicly accessible FCOI policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module). The information is provided on an institutional level as part of an institution's IPF, rather than on a grant-specific level, so it is not necessary to submit the FCOI policy with each grant application.

The Institution must require each Investigator to disclose their (and their spouse and dependent children) domestic and foreign SFIs that are related to their Institutional responsibilities to the Institution's designated official(s).

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000). Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.

The Institution must require each Investigator (including subrecipient Investigators) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be managed include but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of SFIs (e.g., sale of an equity interest)
- Severance of relationships that create FCOIs.

The information above is only a sample of the regulatory requirements found in 42 CFR Part 50--Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on the NIH Financial Conflict of Interest website.

4.1.11 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

1. ***Airline "Open Skies" Agreement.*** A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and recipients (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and recipients must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

   Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to the Fly America Act page on GSA's website

2. ***Involuntary Rerouting.*** Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. ***Travel To and From the U.S.*** Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. ***Travel Between Points Outside the U.S.*** Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

5. ***Short Distance Travel.*** For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR Part 1910.1030, Blood borne pathogens; 29 CFR Part 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910.
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at on CDC's Strengthening Lab Safety webpage.
- Prudent Practices for Safety in Laboratories (2011), National Research Council, National Academies Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 978-0-309-13864-2).

Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

4.1.13 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos.

NIH recipients may use hESCs that have been approved by NIH in accord with NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved

for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

DHHS regulations for Protection of Human Subjects, 45 CFR Part 46, Subpart A, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR Part 46, Subpart A.

In addition, 45 CFR Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 CFR Part 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance.

4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding

The following uses of hESCs, even if derived from embryos donated in accordance with NIH Guidelines and listed on the NIH Registry, or human induced pluripotent stem cells, are prohibited:

- Research in which hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.

In addition, the derivation of stem cells from human embryos is prohibited in NIH funded research by the annual appropriations ban on funding of human embryo research known as the Dickey Wicker Amendment. NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is also prohibited.

NIH will also not fund research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos.

4.1.14 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines.

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

When obtaining primary human fetal tissue for research purposes, NIH expects recipients to maintain appropriate documentation.

4.1.14.1 Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
  - for therapeutic transplantation research,
  - without any restriction regarding the identity of individuals who may receive the transplantation, and
  - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that they have:
  - obtained the tissue in accordance with the donor's signed statement and
  - fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:
  - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
  - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
  - performed the abortion in accordance with applicable State and local laws.

- The PD/PI must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available on FDA's Safety & Availability (Biologics) webpage.

4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions

For the purposes of this section, HFT from elective abortions is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:

• human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.

• animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.

• derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.

• any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

- The definition of research involving HFT from elective abortions does not include the following:
    - human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion
    - already-established (as of June 5, 2019) human fetal cell lines (e.g., induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
    - derivative products from human fetal tissue or cells (e.g., DNA, RNA, protein) if not derived from elective abortion.
    - human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi if not derived from elective abortion.
    - human fetal cells present in maternal blood or other maternal sources
    - human embryonic stem cells or human embryonic cell lines.
    - research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research)."

NIH requires additional documentation of the use of HFT from elective abortions in research, as NIH does with other research materials and models, to ensure that it is utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. NIH requires applicants to provide detailed information addressing the use of HFT in applications/proposals and reports. These requirements are designed to enable NIH to assess whether extramural research applicants and recipients are adequately assuring compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortion.

NIH requires applicants to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant will use HFT. These additional requirements must be met within existing applicable page limits.

The addition of research involving HFT from elective abortions to a funded NIH grant project is considered an indicator of a change in scope and, due to the additional information required, such changes will require the submission of a competing revision application. Competing revision applications must include all required information, as described below. Administrative supplements to add HFT research will not be allowed. Complex grant mechanisms that include centers/cores with discretionary funds will not be allowed to expand existing HFT funding or to add HFT funded activities, including pilot projects.

Training awards and individual fellowships may not propose research using HFT. In addition, grant mechanisms that include centers with discretionary funds and Other Transaction Authority may not be used to support HFT research.

4.1.15 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR Part 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by NIH or other HHS components.

The HHS regulations state that institutions (whether domestic or foreign)that are engaged in nonexempt research involving human subjects research and institutional boards (IRBs) reviewing research that is subject to the HHS regulations must comply with the regulations at 45 CFR 46 (Revised Common Rule §46.101(a) and Pre-2018 Common Rule §46.101(a)). Recipient institutions "engaged" in human subjects research must provide written assurance that it will comply with the regulatory requirements (Revised Common Rule §46.103(a) and Pre-2018 Common Rule §46.103(a)). The recipient institution provides written assurance by obtaining a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP) and establishing appropriate policies and procedures for the protection of human subjects (Revised Common Rule §46.108(a)(3) & (4) and Pre-2018 Common Rule §46.103(b) (4) & (5)). An institution is engaged in human subjects research if:

1. the institution's employees or agents intervene or interact with human subjects for research purposes;
2. the institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or
3. the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

The OHRP's document entitled Engagement of Institutions in Human Subjects Research provides additional guidance on "engagement".

The HHS regulations at Subparts B, C, and D include additional protections for specific populations as follows:

1. pregnant women, human fetuses and neonates (45 CFR Part 46, Subpart B);
2. prisoners (45 CFR Part 46, Subpart C); and
3. children (45 CFR Part 46, Subpart D).

Certain research activities are exempt from regulatory requirements for an FWA and IRB oversight (Revised Common Rule 46.104(d) and Pre-2018 Common Rule 46.101(b). OHRP guidance states that institutions must adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations. NIH will review the materials submitted by the institution, including the PHS Human Subjects Clinical Trails Information Form of the application, to determine if it can concur with the institution that the proposed activities are covered by the regulations or are in one or more exempt category. For research potentially subject to an exemption, this includes reviewing which category of exemption applies. NIH's review does not relieve the institution of any of its regulatory responsibility to accurately make and implement correct determinations about the research for the entirety of the project or otherwise speak for regulatory entities within HHS.

Unless all research activities meet the criteria for one or more exemptions from 45 CFR Part 46, research involving human subjects may only be conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an Institutional Review Board (IRB) registered with OHRP has reviewed and approved the proposed activity in accordance with the HHS regulations.

In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites. The recipient institution also assumes responsibility for ensuring that all institutions under the award engaged in nonexempt research involving human subjects have a current, approved FWA and must obtain certification of approval by an IRB registered with OHRP, of all nonexempt research involving human subjects before research may begin. When consultants are performing

research involving human subjects on NIH-funded projects, the consultant's institution must obtain an FWA.

The The Human Subjects page of the NIH Grants & Funding website contains additional information and Frequently Asked Questions that are available to help investigators understand how these Federal requirements apply to their research.

Applications will be considered incomplete if they do not address the involvement of human subjects in the PHS Human Subjects and Clinical Trials Information Form of the application. If human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application (referred to as "delayed onset human subjects research" in the NIH grant application instructions), applicants must provide a detailed explanation of why it is not possible to develop definite plans. Prior to the involvement of human subjects the recipient must submit to the NIH awarding IC for prior approval either (1) detailed information as required in the PHS Human Subjects and Clinical Trials Information Form of the application, and meet the FWA and IRB certification requirements, or (2) if all of the research meets the criteria for one or more exemptions, identification of which exemptions(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. Typically, recipients that are part of large clinical research networks or consortia that plan to add new protocols after the award must follow the awarding IC's procedures for approval of new protocols. Institutions with award mechanisms that allow them to select new projects, typically small future research projects (e.g., pilot projects), for support by their NIH award are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including prior approval from the IRB if applicable. They must follow the awarding IC's procedures for prior approval of new protocols and updating the IC on the status of funded projects in annual progress reports which are typically described in the NOFO and/or NoA.

Recipients may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an FWA and IRB approval consistent with 45 CFR Part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.

The use of autopsy materials is governed by applicable State and local law and is not regulated by 45 CFR Part 46.

4.1.15.1 Federalwide Assurance Requirements

The Federalwide Assurance (FWA) commits the organization to compliance with the requirements set forth in 45 CFR Part 46, and the Terms of Assurance. Each institution that is engaged in HHS supported human subjects research must be covered by an FWA approved by OHRP.

When an applicant organization proposes nonexempt research involving human subjects and does not have an FWA, the AOR signature on the application constitutes declaration that the organization will comply with 45 CFR Part 46 and proceed to obtain an FWA. The NIH awarding component will place a restriction in the NoA so that no human subjects research may be conducted under the award until the FWA and certification of IRB review and approval (or certification of institutional determination of exemption, if applicable) have been obtained and accepted by NIH.

Each recipient institution must file its own FWA even if the organization does not operate its own IRB and designates another IRB for that purpose. IRBs must be registered with OHRP before the IRB may be designated on an FWA as reviewing proposed research for the FWA-holding institution.

Organizations that will serve as additional performance sites that are engaged in nonexempt research involving human subjects under the award must obtain an FWA, or, under specified circumstance, may be covered by the recipient's FWA in accordance with the OHRP's Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement.

It is the recipient organization's responsibility to ensure that all sites engaged in research involving human subjects are covered by an appropriate FWA and have IRB approval consistent with 45 CFR Part 46. It also is the recipient's responsibility to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements). A list of organizations with approved assurances is available at the OHRP web site.

No individual may receive NIH grant funds for nonexempt research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an FWA or the individual makes other arrangements with OHRP.

Detailed information concerning FWAs is available on the OHRP web site.

4.1.15.2 Certification of IRB Approval

Recipients must provide a certification to NIH that all nonexempt research involving human subjects has been reviewed and approved by an appropriate IRB, consistent with 45 CFR Part 46 and OHRP guidance. NIH-funded sites in the United States cannot rely on a non-US IRB; therefore, NIH will not accept an approval from a non-US IRB. The date of final IRB approval is the date that all protocols in the proposed research application received IRB review and approval (i.e., the date of the last protocol approval). When human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application or proposal (referred to as "delayed onset human subjects research"), prior to the involvement of human subjects in nonexempt research, the recipient must submit to the NIH awarding IC for prior approval (1) detailed information as required in the Human Subjects and Clinical Trials Information Form of the application, as well as the certification and date of final IRB approval. Note that NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. According to OHRP, in the case of IRB approval with conditions, IRB approval only becomes effective when the IRB has approved all information submitted in response to their conditions.

Certification of IRB approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with OHRP FWAs may wish to proceed with IRB review for those protocols that have not yet received IRB approval and that apply to applications in a fundable range.

Under no circumstances may NIH-supported nonexempt research involving human subjects be initiated prior to obtaining IRB approval and providing the final IRB approval date to NIH. NIH will not allow any funds to be used by recipients where a certification and an IRB approval date has not been provided to the funding IC.

Recipients are also reminded that any changes to study protocols that have been subject to peer review, as well as the addition of new study protocols, require the prior approval of the NIH awarding Institute or Center consistent with Section 8.1.2.5 of the NIHGPS. Such requirements are also generally described in the Notice of Funding Opportunity and/or the Notice of Award.

4.1.15.3 Reporting to Funding Agency and OHRP

Under the HHS regulations, recipient institutions must establish and follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and NIH of any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46 or IRB requirements or determinations; and any suspension or termination of IRB approval(revised Common Rule 45 CFR Part 46.108(a)(4) and pre-2018 Common Rule 45 CFR Part 46.103(b)(5)). Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and NIH (45 CFR Part 46.113). Recipient institutions must also file incident reports promptly with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval. See Guidance on Reporting Incidents to OHRP for more information.

4.1.15.4 OHRP Oversight

OHRP has regulatory responsibility for oversight of recipient compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and the organization's assurance of compliance. Any corrective actions imposed as a result of a compliance oversight evaluation are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

Information about the FWA submission process and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from the OHRP home page.

4.1.15.5 Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all senior/key personnel involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of all sites involved in research activities. This documentation should be included in the cover letter signed by the AOR that accompanies the description of other support, IRB and IACUC approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award. Additional information about this education requirement is available on the Training & Resources – Human Subjects page of the NIH Grants & Funding website.

4.1.15.6 Data and Safety Monitoring

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:

- PD/PI (required),
- IRB (required),
- Independent individual/safety officer,
- Designated medical/research monitor,
- Internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials).

Applications that include clinical trials must include a general description of the data and safety monitoring plan. The description of the data and safety monitoring plan in competing applications will be reviewed by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It must describe the entity that will be responsible for monitoring how adverse events will be reported to the IRB and NIH and, when appropriate, how NIH Guidelines and FDA regulations for INDs and IDEs will be satisfied.

A detailed monitoring plan must be included as part of the research protocol, be submitted to the IRB, and be reviewed and approved by the NIH awarding IC prior to the accrual of human subjects. The awarding IC may specify the reporting requirements for adverse events, which are in addition to the annual report to the IRB. The clinical trial monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by clinical trial monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the IRB.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

For multi-site Phase I and II trials, investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs of participating sites. The frequency of summary reports will depend on the nature of the trial. Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and II clinical trials. However, such plans always should be evaluated for appropriateness for the particular investigation.

All multi-site trials with DSMBs are expected to forward summary reports of adverse events to each responsible IRB so they can address as appropriate to their responsibility reports related to the site. Recipients should address questions on this subject to the NIH PO.

Further information concerning these requirements is found on the NIH Human Subjects Research website and in the SF424 (R&R) application instructions, see section G.500 – PHS Human Subjects and Clinical Trials Information.

4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

For all competing grant applications, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications must include a description

of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient / offeror must provide an acceptable justification for the exclusion.

Scientific review groups at NIH will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

NIH recipients must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports.

Ongoing, non-competing awards and competing applications submitted prior to January 25, 2019, will not be expected to comply with this policy until the recipient submits a competing renewal application. For these projects, the previous policy on the inclusion of children (NOT-98-024) continues to apply.

4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

NIH-conducted and supported Clinical research must conform to the *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations be included in NIH-conducted or supported clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the NIH IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the research would duplicate existing data. Women of childbearing potential should not be routinely excluded from participation in clinical research. The policy applies to research subjects of all ages in NIH-supported clinical research studies (see definition of clinical research). The inclusion of individuals on the basis of sex/gender, race, and ethnicity must be addressed in developing a research design appropriate to the scientific objectives of the study. A proposed outreach program for recruiting should also be included. When an NIH-defined Phase III clinical trial is proposed, investigators must consider whether clinically important sex/gender, racial, and/or ethnic differences in the intervention effect are to be expected and plan the research accordingly. When registering in Clincialtrials.gov, applicable clinical trials as defined in 42 C.F.R. Part 11, that are also NIH-defined Phase III clinical trials must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. For applicable clinical trials that are also NIH-defined Phase III clinical trials, submissions of results to Clinicaltrials.gov must include results of valid analyses by sex/gender and race/ethnicity, as required based on prior evidence.

Investigators must also collect and annually report information on sex/gender, race, and ethnicity in clinical research studies. The OMB minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant projects are described in OMB Directive No. 15. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards include five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: “Hispanic or Latino,” and “Not Hispanic or Latino.”

For more information on policies and procedures related to inclusion: Inclusion Procedures

4.1.15.9 Good Clinical Practice Training for NIH Recipients Involved in NIH-funded Clinical Trials

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6 (R2).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting of clinical trials.

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of NIH funded research involving human subjects.

The GCP policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials. GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6. GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Acceptable GCP courses include the NIAID GCP Learning Center website and National Drug Abuse Treatment Clinical Trials Network.. Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training, and make it available to NIH upon request.

For purposes of Good Clinical Practice training the following definitions apply:

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and

collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

4.1.15.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

NIH requires sites located in the United States engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a single Institutional Review Board (sIRB) as required by the Revised Common Rule (rCR) at 45 CFR Part 46.114 and NIH sIRB Policy, including projects supported by career development (K) and fellowship (F) awards with initial IRB approval on or after January 20, 2020. NIH expects the domestic sites in NIH-funded, multi-site studies to rely on a US sIRB (located in the United States). Foreign sites participating in NIH-funded, multi-site studies will not be expected to use a single IRB.

NIH applicants whose research is subject to the sIRB requirements must provide the name of the sIRB during the Just-in-Time period, before the award is issued. If, in delayed-onset research, an sIRB has not yet been identified, the recipient will provide the name of the sIRB to the funding NIH Institute/Center (IC) prior to initiating the multi-site research study/project.

The applicant may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study/project by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in Chapter 7 (Cost Consideration) and in case of for-profit organizations the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

Recipients are responsible for ensuring that authorization agreements are in place. Copies of authorization agreements and other necessary documentation should be maintained to document compliance, as needed. As appropriate, recipients are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established.

All sites participating in multi-site research studies/projects subject to the sIRB requirements are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR Part 46. Participating sites are responsible for meeting all other regulatory obligations.

NIH sIRB policy does not prohibit participating sites from also reviewing the research under the applicable regulatory framework. This additional review, even if performed by the institution's IRB, is not the regulatory review of the research as that responsibility still remains with the sIRB. Iif this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review

4.1.16 Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving investigational drugs and devices, or other products regulated by the FDA, must comply with all applicable FDA requirements, including those for INDs, IDEs, and human subjects protections. Among other provisions, FDA regulations for human subjects protections are published in 21 CFR Parts 50 and 56 with additional standards found in Parts 312 and 812.

When applicable, the sponsor of the IND/IDE, whether NIH, a recipient, or a third party, is legally responsible for meeting the FDA requirements for sponsors. If the sponsor is also the PI, then the sponsor will need to satisfy FDA’s requirements for sponsor-investigators. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a recipient or to a

pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the recipient. This generally will be the case for larger, multi-site clinical trials. If the recipient is the IND/IDE holder, commonly referred to as an "investigator-initiated IND/IDE," the recipient or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the recipient is ultimately responsible to NIH for ensuring compliance with the applicable requirements for protection of human subjects, including compliance with FDA's requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When NIH funds any part of a clinical study involving an IND or an IDE, NIH must be knowledgeable about any significant communications with FDA concerning the study. The recipient organization must report certain types of FDA communications to the NIH awarding IC within 72 hours of receiving a copy of, or upon being informed of, the FDA communication (through the PD/PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the recipient or to the for-profit sponsor)
- Notices of Initiation of Disqualification Proceedings and Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent Agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the recipient even if the recipient or the NIH-funded PD/PI is the sponsor. Failure to comply with this requirement may result in NIH imposing a corrective and/or enforcement action (see Administrative Requirements—Enforcement Actions). FDA communications are considered grant-related records for purposes of retention and access (see Administrative Requirements—Monitoring—Record Retention and Access).

4.1.17 Lobbying Prohibition

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR Part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition under certain circumstances.

Applicants for NIH awards are required to certify and disclose that they:

- have not made, and will not make, such a prohibited payment;
- used or will use non-appropriated funds if they have made or agreed to make such payment; and

- will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

Certifications and disclosures must be filed at the times prescribed in the regulations based on the expected total costs.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in Administrative Requirements—Monitoring—Reporting.

See also Appropriation Public Policy Requirements Mandates Lobbying—Appropriation Prohibition for additional restrictions.

4.1.18 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and recipient-prepared reports, publications, and other grant-related documents should be in metric. See Construction Grants chapter in IIB for requirements for metric usage in construction activities.

4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education

Section 588 of the National Defense Authorization Act of 1995, amended (10 U.S.C. §983), precludes NIH grant awards to institutions of higher education that DoD determines have an anti-Reserve Officer Training Corps (ROTC) policy or practice (regardless of when implemented) that either prohibits or, in effect, prevents the Secretary of Defense from gaining entry to campuses or access to students or information for military recruiting. DoD publishes each determination of ineligibility in the Federal Register as well as publishing, once every 6 months, a list of all currently ineligible schools. If DoD determines that an institution is ineligible during an ongoing project period, NIH will suspend support of current and future grant awards as provided in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. Funding eligibility may be restored on the basis of new information provided by DoD.

4.1.20 National Environmental Policy Act

All NIH grants, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, recipients are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from grant-supported activities, or certify that no such impacts will arise upon receipt of a grant award. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.

3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to other public policy requirements for grants for construction and alteration and renovation activities discussed more fully in the Construction chapter — Construction, Modernization, or Major Alteration and Renovation of Research Facilities—Public Policy Requirements.

4.1.21 Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of their signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against them should not be listed as a participant in an application for an NIH grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants.

4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program

4.1.22.1 PEPFAR Agreements

Specific terms and conditions concerning prostitution and sex trafficking apply to all grants awarded under the U.S. President’s Emergency Plan for AIDs Relief (PEPFAR) program. These are:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B. The following definitions apply for purposes of this provision:
    1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.
    2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
    3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

C. The Recipient must insert this provision, which is a standard provision, in all subawards or subcontracts.

D. This provision includes express terms and conditions of the award and any violation of it is grounds for unilateral termination of the award by NIH prior to the end of its term.

4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non-Governmental Organizations (NGOs)

Additional requirements regarding the opposition to prostitution and sex trafficking may be applied to grants awarded under PEPFAR and issued to foreign Non-Governmental Organizations (NGOs) directly supported by or subrecipients of U.S. public or private NGOs. Subject to the United States Supreme Court's decision in Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al., 133 S. Ct. 2321 (2013) and subsequent proceedings, the terms and conditions for such agreements with foreign NGOs may include the following:

A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

B. 1. Except as provided in (B)(2) and (B)(3), by accepting this award or any subaward, a non-governmental organization or public international organization recipient / sub-recipient agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. Any enforcement of this clause is subject to*Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al.*, 133 S. Ct. 2321 (2013) and subsequent proceedings.

2. The following organizations are exempt from (B)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

3. Contractors and subcontractors are exempt from (B)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

4. Notwithstanding section (B)(3), not exempt from (B)(1) are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:

   i. Providing supplies or services directly to the final populations receiving such supplies or services in host countries;

   ii. Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

   iii. Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

C. The following definitions apply for purposes of this provision:

1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.

3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

D. The recipient shall insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts.

E. This provision includes express terms and conditions of the award and any violation of it shall be grounds for termination of the award by NIH prior to the end of its term.

4.1.23 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library

services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient substance or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

4.1.24 Public Health Security

4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available here, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

Research involving select agents and recombinant or synthetic nucleic acid molecules also is subject to *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. *NIH Guidelines* apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research.

4.1.24.1.1 Select Agents

4.1.24.1.1.1 Select Agent Awards to U.S. Institutions

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR Part 73 and 9 CFR Part 121 and Section 3 of 7 CFR Part 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and International Organizations

Foreign Organizations and International Organizations who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all

select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Recipients must be willing to address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents

Recipients who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds for any work directly involving the select agent at the U.S. institution. No funds can be used for research involving select agents if the final registration certificate is denied. Before using NIH funds for any work directly involving the select agents at a foreign subrecipient, the U.S. recipient must provide information from the foreign organization satisfactory to NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by these funds. Recipients must be willing to address the following key elements appropriate for the foreign organization: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73 are followed. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.2 Dual Use Research of Concern

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences "Dual Use Research of Concern" (DURC). DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Despite its value and benefits, some research may be misused for harmful purposes. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipient institutions and its investigators in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy and to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Institutions must establish an Institutional Review Entity (IRE) which must review research involving these agents or toxins to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR), as required by the U.S. Government's DURC Policy, to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of the DURC policy role. The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

For research that may be considered DURC, NIH will work collaboratively with the institution and investigators to develop a risk mitigation plan, which may be implemented through a term of award and that NIH must approve. For example, NIH may request that institutions periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal.

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention

The United States is one of 175 States Parties to the Chemical Weapons Convention (CWC), which prohibits the development, production, stockpiling, and use of chemical weapons (CW). The CWC does not prohibit production, processing, consumption, or trade of related chemicals for peaceful purposes, but it does establish a verification regime to ensure such activities are consistent with the object and purpose of the treaty.

NIH researchers engaged in activities involving these chemicals, especially Schedule 1 chemicals, may be required to submit declarations and/or reports to the Bureau of Industry and Security (BIS) and may be subject to inspection by the Organization for the Prohibition of Chemical Weapons, which administers the CWC. In addition, trade in certain chemicals with States not Party to the CWC may be prohibited or subject to an export license and or end-use certificate.

Schedule 1 chemicals include, but are not limited to, the toxic chemicals sarin, soman, tabun, VX, sulfur mustards, Lewisites, saxitoxin, ricin, and nitrogen mustards. More information about the U.S. CWC, including complete lists of Schedule 1, 2, and 3 chemicals under the CWC may be found at on the U.S. Chemical Weapons Convention website. Federal regulations that apply to the CWC are 15 CFR CHAPTER VII, SUBCHAPTER B, PARTS 710-722, SUBCHAPTER C, PARTS 730-774; 22 CFR CHAPTER I, PART 103, PARTS 120-130. These CRFs and other applicable safety standards issued by the Department of Commerce and Department of State are available on the Chemical Weapons Conventions Regulations webpage.

4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

As required by Section 403C of the Public Health Service Act, each institution receiving an NIH award for the training of graduate students for doctoral degrees must provide information on completion rates and time to degree to all applicants to doctoral programs supported by NIH training awards. Specifically, institutions must provide applicants with the following information for the programs to which they apply:

- The percentage of students admitted for study who successfully attain a doctoral degree, and
- The average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

Institutions **affected** by this Assurance and information disclosure requirement are doctoral degree granting institutions that receive any of the following institutional training grant awards or cooperative agreements from NIH for the doctoral training of graduate students:

- D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

Institutions are **not affected** by this requirement if they:

- Receive only individual NIH fellowship awards.
- Provide training only to undergraduate or master's level students supported through one of the activity codes listed above.
- Provide only short-term training to doctoral-level health professional students through one of the activity codes listed above.
- Receive an award for one or more of the activity codes for doctoral training of graduate students, but do not confer doctoral degrees themselves (e.g., teaching hospitals).
- Receive an institutional training grant award for doctoral training of graduate students from a Public Health Service Agency other than NIH.

In complying with this Assurance and information disclosure requirement, institutions may decide how best to present the required information to applicants and may wish to consider consolidating data by department or broad program to which candidates apply, or providing additional information in order to provide context.

Recipients with awards for any of the activity codes listed above are also required to provide corresponding information on trainees supported by each of their awards when submitting a renewal application or RPPR.

4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules

4.1.26.1 Scope and Availability

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2019 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecules.

According to *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3)molecules that result from the replication of those described in (1) or (2). *NIH Guidelines* apply to both basic and clinical research studies.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. The recipient should carefully review *NIH Guidelines* in its entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Research involving recombinant or synthetic nucleic acid molecules and select agents also is subject to pertinent CDC and USDA regulations, 42 CFR Part 73, Select Agents and Toxins; and 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins.

4.1.26.2 Institutional Biosafety Committee

Each organization that conducts research involving recombinant or synthetic nucleic acid molecules, including contractors under grants, must have policies and procedures to ensure compliance with NIH

Guidelines and must establish a standing IBC. The IBC is required to review experiments involving recombinant or synthetic nucleic acid molecules to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with NIH Guidelines. Section IV of NIH Guidelines specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to NIH. At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member. Organizations can register their IBC with NIH on-line by utilizing the IBC Registration Management System (RMS).

4.1.26.3 Investigators and Institutional Staff

Section IV of *NIH Guidelines* also specifies the roles and responsibilities of PIs, biological safety officers (BSOs) and recipient institutions with respect to the safe conduct and oversight of recombinant or synthetic nucleic acid molecules. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by *NIH Guidelines*.

4.1.27 Research Misconduct

Title 42 CFR Part 93, PHS Policies on Research Misconduct (the "PHS regulation"), Subpart C, "Responsibilities of Institutions" specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. Research misconduct is defined by Subpart A of 42 CFR Part 93 as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Subpart D, "Responsibilities of the U.S. Department of Health and Human Services," specifies that ORI has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities.

To be eligible for PHS funding, domestic and foreign institutions must have approved assurances and required renewals on file with ORI. The responsible institutional official must assure on behalf of the institution that the institution (1) has written policies and procedures in compliance with 42 CFR Part 93 for inquiring into and investigating allegations of research misconduct in PHS-supported research and (2) complies with its own policies and procedures and the requirements of 42 CFR Part 93. In addition, recipient institutions must foster a research environment that promotes the responsible conduct of research. Domestic and foreign subrecipient institutions must also maintain an assurance by submitting form PHS-6315 to ORI. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and April 30 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the recipient has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The recipient must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR Part 93, Subpart C. The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to provide technical assistance to any institution that is responding to an allegation of research misconduct involving PHS funds. NIH IC staff members are available to provide guidance and to work with recipient institutions to protect funded projects from the adverse effects of research misconduct.

The recipient institution's engagement with ORI as provided in 42 CFR Part 93 does not substitute for its engagement with NIH to ensure ongoing compliance with the terms and conditions of award. When the recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of an NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH. If the recipient institution determines that a change of scope or a change of PD/PI or other senior/key personnel is required, the institution must promptly obtain approval from the NIH funding Institute or Center Grants Management Officer. When a recipient institution finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, NIH has a need to know this information, and the institution must immediately provide information on the affected research to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality provision at, 42 CFR Part 93.108. The final institutional investigation report must be submitted to ORI, as outlined in Subpart C of 42 CFR Part 93.

NIH retains the authority to provide oversight regarding the management of grants and cooperative agreements. Accordingly, NIH may take action(s) to protect the health and safety of the public, including research participants, to promote the integrity of the PHS supported research and research process, and to conserve public funds. When a recipient fails to comply with the terms and conditions of award, NIH may take one or more enforcement actions including disallowance of costs, withholding of further support, or suspension or termination of the grant. These actions are described in Administrative Requirements—Enforcement Actions.

Where research misconduct has affected data validity or reliability, ORI or NIH may request that the recipient and its employee/collaborator authors submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply, NIH may invoke its rights, under 2 CFR Part 200.315, to access the data (including copyrightable material developed under the award), and may then have the data reviewed, and notify the journal.

4.1.28 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages recipients to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

4.1.29 Smoke-Free Workplace

NIH strongly encourages recipients to provide smoke-free workplaces and to promote the nonuse of tobacco products. NIH defines the term "workplace" to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

4.1.30 Standards of Conduct

NIH requires recipients to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the recipient may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The recipient is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, the recipient is required to notify the NIH of an identified financial conflict of interest (FCOI) by submitting the FCOI report to NIH via the eRA Commons FCOI Module (see 4.1.10, Financial Conflict of Interest). If a suspension or separation action is taken by a recipient against a PD/PI or other senior/key personnel under an NIH grant, the recipient must request prior approval of the proposed replacement as specified in Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements.

The recipient must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the HHS OIG .

4.1.31 Text Messaging While Driving

Executive Order 13513 (E.O. 13513) requires each Federal agency to encourage contractors, subcontractors, and grant and cooperative agreement recipients and subrecipients to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles or Government Owned Vehicles, or while driving Personally Owned Vehicles when on official Government business or when performing any work for or on behalf of the Government.

To further the requirement of encouraging such policies, NIH encourages recipients to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the recipient agency's text messaging policy while off duty.

For the purposes of this policy and pursuant to E.O. 13513, the following definitions apply:

a. ''Texting'' or ''Text Messaging'' means reading from or entering data into any handheld or other electronic device, including for the purpose of SMS texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.

b. ''Driving'' means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign, or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.

4.1.32 Trafficking in Persons

This government-wide award term implements Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR Part 175.A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a subrecipient —

a. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;

b. Procures a commercial sex act during the period of time that the award is in effect; or

c. Uses forced labor in the performance of the award or subawards under the award.

4.1.33 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see Public Health Security and Bioterrorism Preparedness and Response Act in this section).

4.1.34 Responsibility/Qualification Information in SAM.gov

NIH award recipients are subject to the reporting requirements established by Public Law 112-239, National Defense Authorization Act for Fiscal Year 2013 and provided in Appendix XII to 2 CFR Part 200, NIH recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000

must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semi-annual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200.

4.1.35 Mandatory Disclosures

Consistent with 2 CFR Part 200.113, NIH applicants and recipients must disclose, in a timely manner, in writing to the NIH awarding IC and the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially impacting the federal award. Subrecipients must disclose, in a timely manner, in writing to the pass-through entity and the HHS OIG all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the NIH awarding IC and to the HHS OIG at the following address:

NIH CGMO listed on the NoA for the IC that funded the grant (See Part III: Points of Contact 20 INSTITUTES AND CENTERS)

AND

U.S. Department of Health and Human Services

Office of Inspector General

ATTN: Mandatory Grant Disclosures, Intake Coordinator

330 Independence Avenue, SW, Cohen Building

Room 5527

Washington, DC 20201

URL: https://oig.hhs.gov/fraud/report-fraud/index.asp

(Include "Mandatory Grant Disclosures" in the subject line")

Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or

Email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 2 CFR Part 200.339. Remedies for noncompliance and Administrative Requirements – Enforcement Actions, including suspension or debarment (See 2 CFR Part 180 and 376, 31 U.S.C.3321 and Public Policy Requirements and Objectives— Debarment and Suspension), as necessary and appropriate.

4.1.36 Never Contract with the Enemy

Federal awarding agencies and recipients are subject to the regulations implementing Never Contract with the Enemy in 2 CFR Part 183. The regulations in 2 CFR Part 183 affect covered contracts, grants and cooperative agreements that are expected to exceed $50,000 within the period of performance, are

performed outside the United States and its territories, and are in support of a contingency operation in which members of the Armed Forces are actively engaged in hostilities.

4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

Recipients and subrecipients are prohibited from expending loan or grant funds to: (1) Procure or obtain; (2) Extend or renew a contract to procure or obtain; or (3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

(i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

(ii) Telecommunications or video surveillance services provided by such entities or using such equipment.

(iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

COVERED FOREIGN COUNTRY means the People's Republic of China.

In implementing the prohibition under section 889 of the NDAA, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions, and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.

4.2 APPROPRIATION MANDATES

The following statutory provisions limit the use of funds on NIH grants, cooperative agreements, and contract awards. These are provided separately in this section since they are subject to change annually based on specific appropriation language that restricts the use of grant funds. References to "Act" in these sections refer to the governing HHS annual appropriation Act. A list of Appropriation Mandates applicable to each fiscal year can be found on the OER web site.

4.2.1 Acknowledgment of Federal Funding

In accordance with Public Law 101-166, Section 511, known as the Steven's Amendment, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the dollar amount of the total costs financed by nongovernmental sources, only for NIH programs that require cost-sharing.

4.2.2 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

4.2.3 Gun Control

NIH funds may not be used, in whole or in part, to advocate or promote gun control.

4.2.4 Human Embryo Research and Cloning Ban

NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism not protected as a human subject under 45 CFR Part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Furthermore, per the NIH Director's Statement of April 28, 2015, NIH will not fund any use of gene-editing technologies in human embryos.

In addition to the statutory restrictions on human fetal research under subsection 498((b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

4.2.5 Lobbying—Appropriation Prohibition

NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State legislature or local legislature itself or designed to support or defeat any proposed or pending regulation administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. No part of any governing appropriation act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. No part of any governing appropriation Act shall be used for any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control, except as described above. Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates—Gun Control and Cost Considerations—Allowability of Costs and Activities.

4.2.6 Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage (see also 4.1.5 Controlled Substances).

4.2.7 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term ‘‘health benefits coverage’’ means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

4.2.8.1 Exceptions to Restrictions on Abortions

A. The limitations established in the preceding section shall not apply to an abortion —
   1. If the pregnancy is the result of an act of rape or incest; or
   2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

B. Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).

C. Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).

D.
   1. None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.
   2. In this subsection, the term ‘‘health care entity’’ includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

4.2.9 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. However, this limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health

department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law

4.2.10 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the Salary Cap Summary page of the NIH Grants & Funding website.

4.2.10 Restriction of Pornography on Computer Networks

"(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

4.2.11 Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates

Section 515 of the FY2014 Consolidated Appropriations Act included an additional legislative mandate regarding this requirement:

"None of the funds made available in this Act may be used to request that a candidate for appointment to a Federal scientific advisory committee disclose the political affiliation or voting history of the candidate or the position that the candidate holds with respect to political issues not directly related to and necessary for the work of the committee involved."

5 THE NOTICE OF AWARD

The Notice of Award (NoA) is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to affect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs for NIH policy on the allowability of pre-award costs).

Notice of Award Page One

Effective October 1, 2020, HHS implemented a standardized page one of the NoA that serves as the first page of every HHS NoA for all discretionary awards. The standardized page one incorporates the following data elements:

- HHS Operating Division
- Federal Award Identification Number
- Federal Award Date

- Recipient Information
  - Recipient Name
  - Congressional District of Recipient
  - Payment System Identifier (also known as Entity Identification Number)
  - Employer Identification Number
  - Data Universal Numbering System
  - Recipient's Unique Entity Identifier
  - Project Director or Principal Investigator
  - Authorized Official
- Federal Agency Information
  - Awarding Agency Contact Information
  - Program Official Contact Information
- Federal Award Information
  - Award Number
  - Unique Federal Award Identification Number
  - Statutory Authority
  - Federal Award Project Title
  - Assistance Listing Number (formerly / also known as CFDA Number)

- Assistance Listing Program Title (formerly / also known as CFDA program title)Name
- Award Action Type
- Is this Award R&D?
- Summary Federal Award Financial Information
  - Budget Period Start and End Date
  - Total Amount of Federal Funds Obligated by this Action
    - Direct Cost Amount
    - Indirect Cost Amount
  - Authorized Carryover
  - Offset
  - Total Amount of Federal Funds Obligated this Budget Period
  - Total Approved Cost Sharing or Matching, where applicable
  - Total Federal and Non-Federal Approved this Budget Period
  - Project Period Start and End Date
  - Total Amount of the Federal Award, including Approved Cost Sharing or Matching, this Project Period
- Authorized Treatment of Program Income
- Grants Management Officer Signature
- Remarks

Remainder of the NIH NoA

Additionally, the remainder of the NIH NoA sets forth pertinent information about the grant in Section I (Award Data), Section II (Payment Information), and Sections III and IV (Applicable Terms and Conditions of Award). This additional information, includes, but not limited to, the following:

- Cumulative budget approved by the NIH awarding IC
- Amount of anticipated future-year commitments (if applicable)
- Names of the cognizant IC PO, GMO, and GMS
- Indirect cost rate for the Federal award (including if the de minimis rate is charged per 2 CFR Part 200.414)
- Applicable terms and conditions of award, either by reference or inclusion
- Federal award performance goals (as required by the periodic report in the RPPR or in the final RPPR when applicable)
- Any restriction on the use of funds

Note: If applicable, section III of the NoA will also reference an institution’s participation in the current phase of the Federal Demonstration Partnership (FDP).

As specified in the NoA, all awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 2 CFR Part 200. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

A recipient indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the recipient cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH's determination of applicable terms and conditions of award or a GMO's denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in Administrative Requirements—Grant Appeals Procedures). Once the award is accepted by the recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

5.1 NOTICE OF AWARD NOTIFICATION

NIH notifies the recipient organization via e-mail when an award has been issued-i.e., on the Federal award date. In order to allow for the e-mail notification of the NoA, recipient organizations must register a valid e-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique e-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the recipient organization to maintain a current and accurate e-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated e-mail notification process. Recipients that do not maintain a current NoA notification e-mail address will be responsible for accessing NoAs via the eRA Common.

On the Federal award date, the NoA is made available to recipient officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

In addition to e-mail notifications, there is a public query *Quick Query – Search for an Issued NoA)* available on the eRA web site to generate a list of awards issued to an organization over a selected period. The organization's Institution Profile File (IPF) Number is required in order to use the query.

5.2 ASSOCIATED APPLICATIONS AND/OR AWARDS

For some special initiatives a project or program may be funded by multiple awards that are associated with the others through specific terms and conditions. These terms include any reporting requirements that would need to be coordinated in future years. When multiple awards are issued for a particular project/program at different institutions, the coordination required among the recipient institutions administering the awards will be documented in the specific terms and conditions.

5.3 FUNDING

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget

periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC based on:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support. A recipient may appeal this decision only if the withholding was for the recipient's failure to comply with the terms and conditions of a previous award (see Administrative Requirements—Grant Appeals Procedures).

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31 of the fifth fiscal year after the year of availability. This provision may limit the availability of funds for carryover. It may also limit or eliminate the authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

5.4 BUDGET

Each NoA sets forth the amount of funds awarded. The amount may be shown either as a categorical (line item) budget or as an amount for total direct costs (not broken down by category) and an amount

for F&A costs, if applicable. Modular awards represent a type of award made without a categorical budget (see Modular Applications and Awards chapter in IIB). The recipient has certain rebudgeting flexibility within the overall amount awarded (see Administrative Requirements—Changes in Project and Budget). The recipient may be required to provide matching funds under construction awards as specified in Construction Grants—Matching in IIB as well as under other NIH programs or awards if specified in the Notice of Funding Opportunity.

5.5 ADDITIONAL TERMS AND CONDITIONS

In addition to, or in lieu of, the standard terms and conditions of award specified in the NIHGPS, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the recipient's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with applicable regulations including 42 CFR Part 52.9 and 2 CFR Part 200.339 and 45 CFR Part 75.371. For example, NIH could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the recipient in taking any necessary corrective action.

6 PAYMENT

The PMS is a centralized grants payment and cash management system, operated by HHS PSC, PMS. HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this chapter. Payments under NIH grants generally are made as advance payments. NIH grant payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements, as implemented by 2 CFR Part 200.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds in this manner. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by recipients to consortium participants and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to PSC/PMS (see Part III).

6.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

6.2 CASH REQUEST

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a recipient's cash management must be closely monitored (for example, recipients whose financial management systems do not meet the standards specified in 2 CFR Part 200.302) or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that a recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Enforcement Actions—Modification of the Terms of Award).

If the cash request is for an advance payment, the recipient may request grant funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the recipient electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

6.3 INTEREST EARNED ON ADVANCES OF GRANT FUNDS

Except as provided in 2 CFR Part 200.305(b)(8), any NIH recipient subject to the requirements of 2 CFR Part 200 that receives advance payments must maintain those advances in an interest-bearing account.

Recipients are expected to promptly return any funds not spent within three business days. As provided in 2 CFR Part 200.305(b)(9) subject to the requirements of 2 CFR Part 200 and to the extent required by law, interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the non-Federal entity for administrative expense.

6.4 IMPROPER PAYMENTS ELIMINATION AND RECOVERY IMPROVEMENT ACT

The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (PL 112-248), signed into law on January 10, 2013, established the Do Not Pay Initiative to reduce improper payments or awards. Improper payments occur when funds go to the wrong recipient, the recipient receives the incorrect amount of funds (including overpayments and underpayments), documentation is not available to support a payment, or the recipient uses funds in an improper manner. Incorrect amounts are overpayments or underpayments that are made to eligible recipients (including inappropriate denials of payment or service, any payment that does not account for credit for applicable discounts, payments that are for an incorrect amount, and duplicate payments). When an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an improper payment. When establishing documentation requirements for payments, agencies should ensure that all documentation requirements are necessary and should refrain from imposing additional burdensome documentation requirements. Interest or other fees that may result from an underpayment by an agency are not considered an improper payment if the interest was paid correctly. These payments are generally separate transactions and may be necessary under certain statutory, contractual, administrative, or other legally applicable requirements.

HHS has implemented provisions of IPERIA through integrating use of the Do Not Pay system into the current payment processes managed by the PMS, HHS.

7 COST CONSIDERATION

7.1 GENERAL

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed in Administrative Requirements—Changes in Project and Budget.

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see Administrative Requirements—Closeout).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and recipients. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

7.2 THE COST PRINCIPLES

In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization (regardless whether domestic or foreign) making the expenditure. For example, a for-profit organization collaborating with a university recipient would be subject to the cost principles for for-profit organizations, while the university would be subject to the cost principles for Institutions of Higher Educations (IHEs).

The cost principles are set forth in HHS regulations at 2 CFR Part 200, Subpart E. For-profit organizations are subject to the cost principles located at 48 CFR Part 31.2 Federal Acquisition Regulation.

The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in Ruth L. Kirschstein National Research Service Awards in IIB.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 2 CFR Part 200.302 for financial management systems.

The cost principles address four tests to determine the allowability of costs. The tests are as follows:

- ***Reasonableness (Including Necessity).*** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.
- ***Allocability.*** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see Cost Considerations—Allocation of Costs and Closely Related Work).
- ***Consistency.*** Recipients must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- ***Conformance.*** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. Cost Considerations—Allowability of Costs/Activities provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or recipient. IIB contains additional information on allowability of costs for particular types of grants, recipients, and activities.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

7.3 DIRECT COSTS AND FACILITIES AND ADMINISTRATIVE COSTS

Direct costs are any cost that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned (allocated) to such activities relatively easily with a high degree of accuracy. Direct costs may include, but are not limited to, salaries, travel, equipment, and supplies directly supporting or benefiting the grant-supported project or activity. If directly related to a specific award, certain costs that otherwise would be treated as indirect costs may also be considered direct costs.

Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. These are referred to as indirect costs, also called Facilities and Administrative costs (F&A). Facilities operation and maintenance costs, depreciation, and administrative

expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs. Note, the term facilities and administrative costs and the term indirect costs may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as indirect costs.

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs in IIB.) If a recipient waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the recipient under that award.

7.4 REIMBURSEMENT OF FACILITIES AND ADMINISTRATIVE COSTS

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the recipient has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects (see Administrative Requirements—Management Systems and Procedures—Financial Management System Standards).

F&A rates are negotiated by CAS, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency for indirect costs and must conform to cost policies in the NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from DCA or DFAS (see Part III). CAS should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of 2 CFR Part 200, Subpart E-Cost Principles.

Consistent with 2 CFR Part 200.414(f), any non-Federal entity, including for-profit organizations, that does not have a current negotiated (including provisional) F&A rate, except for those non-Federal entities described in 2 CFR Part 200, Appendix VII, Section D(1)(b) and 45 CFR Part 75, Appendix VII may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. No documentation is required to justify the 10% de minimis indirect cost rate. As described in 2

CFR Part 200.403 and 45 CFR Part 75.403, costs must be consistently charged as either indirect or direct costs but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

If a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used. If no approved rate exists, the pass-through entity must determine the appropriate rate in collaboration with the subrecipient, which is either: the negotiated indirect cost rate between the pass-through entity and the subrecipient; which can be based on a prior negotiated rate between a different PTE and the same subrecipient. If basing the rate on a previously negotiated rate, the pass-through entity is not required to collect information justifying this rate but may elect to do so; or the de minimis indirect cost rate. The pass-through entity must not require use of a de minimis indirect cost rate if the subrecipient has a Federally approved rate. Subrecipients can elect to use the cost allocation method to account for indirect costs. The cost principles are designed to provide that Federal awards bear their fair share of costs recognized under these principles.(See 2 CFR 200.100(c) and 45 CFR Part 75.100). Pass-through entities may, but are not required, to negotiate a rate with a proposed subrecipient that asks to do so. If the consortium is with a for-profit entity, such as a small business, the organization must have an established F&A cost rate before they can charge F&A costs. The default small business rate of 40 percent is only applicable to SBIR and STTR applications.

Regardless of the type of recipient, the rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and recipient type. Generally, recipients may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants to IHEs is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding (See 2 CFR 200 Appendix III Section C(7)(b)). Therefore per 2 CFR 200 Appendix IIIIHEs may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (final, fixed or predetermined) rates rather than provisional rates (See 2 CFR 200 Appendix III Section C(7)(a)).For recipients other than IHEs, F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials. For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or recipient did not submit a timely F&A cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the recipient's F&A cost proposal submission. This provision does not affect local governmental agencies that are not required to submit their F&A (indir-

ect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is before 1 calendar month prior to the beginning date of the grant budget period.
- NIH restores funds previously recaptured as part of a recipient's unobligated balance.
- The recipient is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- ***Fellowships.*** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
- ***Construction and Modernization.*** F&A costs will not be provided on construction or modernization grants.
- ***Grants to Individuals.*** F&A costs will not be provided on awards to individuals.
- ***Grants to Federal Institutions.*** F&A costs will not be provided on grants to Federal institutions.
- ***Grants in Support of Scientific Meetings (Conference Grants).*** F&A costs will not be provided under grants in support of scientific meetings.
- ***Endowment Grants.*** F&A costs will not be provided for endowment grants.

NIH limits the amounts included in the F&A base for the following type of costs:

- ***Genomic Arrays (GA)*** are a high-throughput genetic analysis technology which enables the study of genetic variation and gene expression at high resolution. Approaches such as genome-wide association and gene expression profiling often depend upon manufactured products known as microarrays or bead arrays. These tools are exceptional among laboratory supplies in that they are almost always procured from a commercial source; have a relatively high unit cost and are often utilized in large numbers. The treatment of the costs for purchase of GA as "supplies" in these specialized award budgets at high levels of usage would result in the application of F&A cost recovery that is disproportionate to the actual administrative burden associated with the relatively high cost of the procurement of these GA. Accordingly, for purposes of budgeting for and award of high volume purchases of GA in excess of $50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead, the requested and reimbursed costs for GA will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore, for each budget year, the first $50,000 of GA will be treated as "supplies", and any GA in excess of $50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

NIH provides F&A costs without the need for a negotiated rate under the following classes of awards:

- ***Research Training and Education Grants (e.g., R25), and K Awards.*** F&A costs under Kirschstein-NRSA institutional research training grants, educational and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and consortiums in excess of $25,000. State, local, and Indian tribes (or "federally recognized Indian tribes") may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.
- ***Grants to Foreign Organizations and International Organizations.*** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allowability.*

7.5 COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers to NIH grants by recipients, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the recipient, consortium participant, or contractor. An explanation merely stating that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Recipients must maintain documentation of cost transfers, pursuant to 2 CFR Part 200.337, and must make it available for audit or other review (see Administrative Requirements—Monitoring—Record Retention and Access). The recipient should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur, recipients are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. NIH also may require a recipient to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors recipient expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the recipient's associated budget, including the availability of unobligated balances. Although NIH allows recipients certain flexibilities with respect to rebudgeting (see Administrative Requirements—Changes in Project and Budget), NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

The GMO may review recipient cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved budget and period of performance. In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

7.6 ALLOCATION OF COSTS AND CLOSELY RELATED WORK

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the recipient's financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction).

7.7 APPLICABLE CREDITS

The term applicable credits refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or F&A cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the recipient's FFR, whether those credits accrue during or after the period of grant support. (See Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout—Final Federal Financial Reports.) The NIH awarding IC will notify the recipient of any additional actions that may be necessary.

7.8 SERVICES PROVIDED BY AFFILIATED ORGANIZATIONS

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Sometimes, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as an NIH recipient, includes the cost of these services in its F&A proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a recipient foundation are allowable for reimbursement under NIH grants only if at least one of the following conditions is met:

- The affiliated organization is charged for, and is legally obligated to pay for, the services provided by the parent organization.
- The affiliated organizations are subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in their official capacity approves such expenditures.
- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the recipient foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the recipient foundation that discretion.

If none of the above conditions are met, the costs of the services provided by the parent organization to the recipient foundation are not allowable for reimbursement under an NIH grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Foundations that represent already existing recipient organizations should contact DGP, OPERA before attempting to become a separately recognized applicant organization.

7.9 ALLOWABILITY OF COSTS/ACTIVITIES

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. This section is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of whether or not a cost is allowed.

This section also includes NIH-specific requirements concerning costs and activities. The allowability of costs under specific NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which take precedence over the general discussion provided here. Specific program requirement may also be covered in other sections of the NIHGPS. Applicants or recipients that have questions concerning the allowability of particular costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the recipient's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any costs or activities that require NIH prior approval constitutes the prior approval for those costs or activities. The recipient is not required to obtain any additional approval for those costs/activities. Post-award requests to incur costs or undertake activities requiring prior approval that are not described in the approved application are subject to the requirements in Administrative Requirements—Changes in Project and Budget.

Consortium participants and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the recipient to be able to comply with the terms and conditions of the NIH grant.

The cost principles do not address profit or fee. NIH policy allows the payment of fee on SBIR/STTR grants (see Grants to For-Profit Organizations chapter in IIB) but NIH will not provide profit or fee to any other type of recipient under any other grant program or support mechanism. A fee may not be paid by a recipient to a consortium participant, including a for-profit organization. However, a fee (profit)

may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

7.9.1 Selected Items of Cost

Exhibit 5: Selected Items of Cost

The table presents specific items that may or may not be included in the cost portion of grants

Items	Explanation of Allowable Costs
Advertising and Public Relations	1. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television, direct mail, exhibits, electronic or computer transmittals, and the like. 2. The only allowable advertising costs are those which are solely for: a. The recruitment of personnel required by the non-Federal entity for performance of a Federal award (See also 2 CFR Part 200.463); b. The procurement of goods and services for the performance of a Federal award; c. The disposal of scrap or surplus materials acquired in the performance of a Federal award except when non-Federal entities are reimbursed for disposal costs at a predetermined amount; or d. Program outreach and other specific purposes necessary to meet the requirements of the Federal award. 3. The term ‘‘public relations’’ includes community relations and means those activities dedicated to maintaining the image of the non- Federal entity or maintaining or relations with the community or public at large or any segment of the public. 4. The only allowable public relations costs are: a. Costs specifically required by the Federal award; b. Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of the Federal award (these costs are considered necessary as part of the outreach effort for the Federal award); or c. Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of funding opportunities, financial matters, etc. 5. Unallowable advertising and public relations costs include the following: a. All advertising and public relations costs other than as specified in paragraphs (2) and (4) of this section; b. Costs of meetings, conventions, convocations, or other events related to other activities of the entity (see also 2 CFR Part 200.432), including: i. Costs of displays, demonstrations, and exhibits; ii. Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and

Items	Explanation of Allowable Costs
	iii. Salaries and wages of employees engaged in setting up and displaying exhibits, making demonstrations, and providing briefings; c. Costs of promotional items and memorabilia, including models, gifts, and souvenirs; d. Costs of advertising and public relations designed solely to promote the non-Federal entity
Alcoholic Beverages	Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.
Alteration and Renovation	Individual A&R projects that are treated as direct costs and that are determined to be minor be subject to the A&R policies specified in this exhibit and in the Construction Grants chapter, as applicable. Individual A&R projects determined to be A&R will be subject to the requirements specified in the Construction Grants chapter. Routine maintenance and repair of the organization's physical plant or equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the recipient's accounting system. A&R costs are not allowable under grants to individuals, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements: • The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. • The A&R is essential to the purpose of the grant-supported project. • The space involved will be occupied by the project. • The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage. • If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.

Items	Explanation of Allowable Costs
	• If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in "Preservation of Cultural and Historic Resources" have been followed. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. A recipient may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting will result in the addition of a major A&R project, NIH will consider the rebudgeting to be a change in scope, and the recipient must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter for prior approval of A&R projects above that dollar level. Under foreign grants or foreign components under domestic grants, major A&R is unallowable. Minor A&R is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations.
Animals	Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (see Public Policy Requirements and Objectives—Animal Welfare). If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the *Cost Analysis and Rate Setting Manual for Animal Resource Facilities* (PDF, 32 MB) — May 2000.
Audiovisual Activities	Allowable for the production of an audiovisual. "Audiovisual" means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. "Production" refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the recipient must submit two copies of the finished product along with its annual or final progress report (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout). The costs of such copies are allowable project costs. Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:

Items	Explanation of Allowable Costs
	The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No._____ from [name of NIH awarding IC]. Its contents are solely the responsibility of [name of recipient organization] and do not necessarily represent the official views of [name of NIH awarding IC].
Audit Services	1. A reasonably proportionate share of the costs of audits required by, and performed in accordance with, the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), as implemented by requirements of 2 CFR Part 200, are allowable. However, the following audit costs are unallowable: a. Any costs when audits required by the Single Audit Act and Subpart F— Audit Requirements of 2 CFR Part 200 have not been conducted or have been conducted but not in accordance therewith; and b. Any costs of auditing a non- federal entity that is exempted from having an audit conducted under the Single Audit Act and Subpart F—Audit Requirements of 2 CFR Part 200 because its expenditures under Federal awards are less than $750,000 during the non- Federal entity's fiscal year. 2. The costs of a financial statement audit of a non-Federal entity that does not currently have a Federal award may be included in the indirect cost pool for a cost allocation plan or indirect cost proposal. 3. Pass-through entities may charge Federal awards for the cost of agreed-upon-procedures engagements to monitor subrecipients (in accordance with Subpart D of 2 CFR Part 200.331 through 200.333) which are exempted from the requirements of the Single Audit Act and Subpart F of 2 CFR Part 200. This cost is allowable only if the agreed-upon-procedures engagements are: a. Conducted in accordance with GAGAS attestation standards; b. Paid for and arranged by the pass-through entity; and c. Limited in scope to one or more of the following types of compliance requirements: activities allowed or unallowed; allowable costs/cost principles; eligibility; and reporting.
Bad Debts	Bad debts (debts which have been determined to be uncollectable), including losses (whether actual or estimated) arising from uncollectable accounts and other claims, are unallowable. Related collection costs, and related legal costs, arising from such debts after they have been determined to be uncollectable are also unallowable. (See also 2 CFR Part 200.428).

Items	Explanation of Allowable Costs
Bonding	1. Bonding costs arise when the Federal awarding agency requires assurance against financial loss to itself or others by reason of the act or default of the non-Federal entity. They arise also in instances where the non-Federal entity requires similar assurance, including: bonds as bid, performance, payment, advance payment, infringement, and fidelity bonds for employees and officials. 2. Costs of bonding required pursuant to the terms and conditions of the Federal award are allowable. 3. Costs of bonding required by the non-Federal entity in the general conduct of its operations are allowable as an indirect cost to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.
Books and Journals	Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs.
Building Acquisition	Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NoA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see Construction Grants—Allowable and Unallowable Costs and Activities in IIB).
Capital Expenditures	See Equipment and Other Capital Expenditures.
Child care Costs	Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see Fringe Benefits and Travel Costs in this exhibit). NRSA Fellowship Grants may also be allowed to incur these costs (see 11.2.9.7 for specific eligibility criteria).
Collection of Improper Payments	The costs incurred by a non-Federal entity to recover improper payments are allowable as either direct or indirect costs, as appropriate. Amounts collected may be used by the non-Federal entity in accordance with cash management standards set forth in 2 CFR Part 200.305. (See Improper Payment).
Communications	Allowable. Such costs include local and long-distance telephone calls, express mail, and postage, and usually are treated as F&A costs.
Conference Grant Costs	See Support of Scientific Meetings (Conference Grants) chapter in IIB for allowability of costs for scientific meetings (conferences).
Consortium Agreements/ Contracts under Grants	Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may require NIH approval as specified in Administrative Requirements—Changes in Project and Budget. (See also Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for policies that apply to the acquisition of routine goods and services and the Consortium Agreements chapter in IIB for policies that apply to recipient collaboration with

Items	Explanation of Allowable Costs
	other organizations in carrying out the grant-supported research).
Construction	Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see Construction Grants chapter in IIB).
Consultant Services	See Professional Services and Salaries and Wages/Intra-IHE Consulting.
Contingency Provisions	Unallowable. Payments made by the NIH awarding IC to the non-Federal entity's "contingency reserve" or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see Reserve Funds in this exhibit). (See also Construction Grants—Allowable and Unallowable Costs and Activities in IIB concerning contingency funds under construction grants).
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (See Taxes in this exhibit).
Depreciation or Use Allowances	Allowable. Such costs usually are treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.
Donor Costs	Allowable as payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. Donor costs are not considered a research patient care expense (see the Research Patient Care Costs chapter in IIB). Also see Incentive Costs in this exhibit.
Drugs	Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.
Dues or Membership Fees	Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds. See also Membership, Subscription, and Professional Activity costs.

Items	Explanation of Allowable Costs
Entertainment Costs	Costs of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the NIH awarding IC.
Equipment and Other Capital Expenditures	The following rules of allowability must apply to equipment and other capital expenditures: 1. Capital expenditures for general purpose equipment, buildings, and land are unallowable as direct charges, except with the prior written approval of the NIH awarding IC or pass-through entity. 2. Capital expenditures for special purpose equipment are allowable as direct costs, provided that items that relate to a change in scope (which may be indicated by a unit cost of $25,000 or more) have the prior written approval of the NIH awarding IC or pass-through entity. 3. Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as a direct cost except with the prior written approval of the NIH awarding IC, or pass-through entity. See Depreciation for rules on the allowability of depreciation on buildings, capital improvements, and equipment. See also Rental Costs of Real Property and Equipment. 4. When approved as a direct charge pursuant to items (1) through (3) above, capital expenditures will be charged in the period in which the expenditure is incurred, or as otherwise determined appropriate and negotiated with the NIH awarding IC. 5. The unamortized portion of any equipment written off as a result of a change in capitalization levels may be recovered by continuing to claim the otherwise allowable depreciation on the equipment, or by amortizing the amount to be written off over a period of years negotiated with the Federal cognizant agency for indirect cost. 6. Cost of equipment disposal. If the non-Federal entity is instructed by the NIH awarding IC to otherwise dispose of or transfer the equipment the costs of such disposal or transfer are allowable. See also Capital Expenditures, Equipment, Special Purpose Equipment, General Purpose Equipment, Acquisition Cost, and Capital Assets.
Federal (U.S. Government) Employees	See Grants to Federal Institutions and Payments to Federal Employees under Grants—Allowable and Unallowable Costs in IIB for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions.
Fines, Penalties, Damages and Other Settlements	Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the NIH awarding IC.

Items	Explanation of Allowable Costs
Fringe Benefits	Fringe benefits are allowances and services provided by employers to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave (vacation, family related, sick or military), employee insurance, pensions, and unemployment benefit plans. Except as provided elsewhere in 2 CFR Part 200, Subpart E, the costs of fringe benefits are allowable provided that the benefits are reasonable and are required by law, non-Federal entity-employee agreement, or an established policy of the non-Federal entity. For policies applicable to tuition remission for students working on grant-supported research projects, see Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit. See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition and Fees in IIB for the allowability of tuition costs for fellows and trainees.
Fringe Benefits / IHE *Tuition/Tuition Remission*	Tuition remission and other forms of compensation paid as, or in lieu of, wages to students under research grants are allowable, provided the following conditions are met: 1. The individual is conducting activities necessary to the Federal award. 2. Tuition remission and other support are provided, in accordance with established institutional policy, of the IHE and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities. 3. During the academic period, the student is enrolled in an advanced degree program at a non-Federal entity or affiliated institution and the activities of the student in relation to the Federal award are related to the degree program. 4. The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work. 5. It is the IHE's practice to similarly compensate students under Federal awards as well as other activities Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to reporting requirements in 2 CFR Part 200.430(i). NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of 2 CFR Part 200, Subpart E. The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at http://grants.nih.gov/training/nrsa.htm). Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project.

Items	Explanation of Allowable Costs
Fringe Benefits / Insurance	Allowable. Insurance usually is treated as an F&A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at all types of recipients only if the research involves human subjects. If so, the insurance must be treated as a direct cost and must be assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. See also Reserve Funds. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in the Ruth L. Kirschstein National Research Service Awards chapter in IIB.
Fringe Benefits / Pension Plan Costs	Pension plan costs which are incurred in accordance with the established policies of the non-Federal entity are allowable, provided that: 1. Such policies meet the test of reasonableness. 2. The methods of cost allocation are not discriminatory. 3. For entities using accrual-based accounting, the cost assigned to each fiscal year is determined in accordance with GAAP. 4. The costs assigned to a given fiscal year are funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 calendar days after each quarter of the year to which such costs are assignable are unallowable. Non-Federal entity may elect to follow the ‘‘Cost Accounting Standard for Composition and Measurement of Pension Costs’’ (48 CFR Part 9904.412). 5. Pension plan termination insurance premiums paid pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1301–1461) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and other penalties imposed under ERISA are unallowable. 6. Pension plan costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity. a. For pension plans financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries.

Items	Explanation of Allowable Costs
	b. Pension costs calculated using an actuarial cost-based method recognized by GAAP are allowable for a given fiscal year if they are funded for that year within six months after the end of that year. Costs funded after the six month period (or a later period agreed to by the cognizant agency for indirect costs) are allowable in the year funded. The cognizant agency for indirect costs may agree to an extension of the six month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal government and related Federal reimbursement and the non-Federal entity's contribution to the pension fund. Adjustments may be made by cash refund or other equitable procedures to compensate the Federal government for the time value of Federal reimbursements in excess of contributions to the pension fund. c. Amounts funded by the non- Federal entity in excess of the actuarially determined amount for a fiscal year may be used as the non- Federal entity's contribution in future periods. d. When a non-Federal entity converts to an acceptable actuarial cost method, as defined by GAAP, and funds pension costs in accordance with this method, the unfunded liability at the time of conversion is allowable if amortized over a period of years in accordance with GAAP. e. The Federal government must receive an equitable share of any previously allowed pension costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
Fringe Benefits / *Severance Pay*	1. Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by non-Federal entities to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, it is required by: a. law, b. employer-employee agreement, c. established policy that constitutes, in effect, an implied agreement on the non- Federal entity's part, or d. circumstances of the particular employment. 2. Costs of severance payments are divided into two categories as follows:

Items	Explanation of Allowable Costs
	a. Actual normal turnover severance payments must be allocated to all activities; or, where the non-Federal entity provides for a reserve for normal severances, such method will be acceptable if the charge to current operations is reasonable in light of payments actually made for normal severances over a representative past period, and if amounts charged are allocated to all activities of the non- Federal entity. b. Measurement of costs of abnormal or mass severance pay by means of an accrual will not achieve equity to both parties. Thus, accruals for this purpose are not allowable. However, the Federal government recognizes its obligation to participate, to the extent of its fair share, in any specific payment. Prior approval by the Federal awarding agency or cognizant agency for indirect cost, as appropriate, is required. 3. Costs incurred in certain severance pay packages which are in an amount in excess of the normal severance pay paid by the non-Federal entity to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the non-Federal entity's assets, are unallowable. 4. Severance payments to foreign nationals employed by the non-Federal entity outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the non-Federal entity in the United States, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC. 5. Severance payments to foreign nationals employed by the non-Federal entity outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the non-Federal entity in that country, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC.
Fundraising and Investment Management Costs	1. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred to raise capital or obtain contributions are unallowable. Fund raising costs for the purposes of meeting the Federal program objectives are allowable with prior written approval from the Federal awarding agency. (See also Proposal Costs). 2. Costs of investment counsel and staff and similar expenses incurred to enhance income from investments are unallowable except when associated with investments covering pension, self-insurance, or other funds which include Federal participation allowed by 2 CFR Part 200. 3. Costs related to the physical custody and control of monies and securities are allowable.

Items	Explanation of Allowable Costs
	4. Both allowable and unallowable fund raising and investment activities must be allocated as an appropriate share of indirect costs under the conditions described in 2 CFR Part 200.413.
Genomic Arrays	Allowable as a direct cost, but with specialized treatment of F&A reimbursement for costs exceeding $50,000 in each budget year. See Cost Considerations-Reimbursement of Facilities and Administrative Costs for more information.
Hazardous Waste Disposal	Allowable; usually treated as an F&A cost.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Hospitalization	See Research Patient Care in this exhibit.
Incentive Costs	Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See Salaries and Wages/Incentive Compensation in this exhibit for incentive payments to employees.
Indemnification	Absent express statutory authority, unallowable if the indemnification would result in liability that is indefinite, indeterminate or potentially unlimited. In those rare cases where authority does allow this cost, it would be reflected in the NoA.
Independent Research and Development Costs	Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.
Intellectual Property (Invention, Copyright, Patent, or Licensing Costs)	Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&A costs, provided they are in accordance with 2 CFR Part 200.448 and are included in the negotiation of F&A cost rates.
Interest	Allowable as an F&A cost for certain assets as specified in 2 CFR Part 200.449. Unallowable for hospitals. (2 CFR Part 200, Appendix IX, I.o.). (See Payment—Interest Earned on Advances of Grant Funds).
IRB or IACUC Costs	Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols, are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.
Laboratory Directed Research &	NIH awards to DOE laboratories will not include the proportionate share of F&A costs for Laboratory Directed Research & Development (LDRD) in accordance

Items	Explanation of Allowable Costs
Development	with the MOU with the Department of Energy dated June 18, 1998, although NIH will not restrict the DOE laboratory contractors from recovering LDRD costs within the total funding included in an award. In addition, DOE has agreed to waive the Overhead Rate on all NIH grant awards to DOE laboratory contractors.
Leave	Allowable for employees as a fringe benefit (see Fringe Benefits in this exhibit). See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave in IIB for NIH policy on leave for fellows and trainees.
Legal Services	Allowable. Generally treated as an F&A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the recipient organization. Before a recipient incurs legal costs that are extraordinary or unusual in nature, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are generally unallowable charges to NIH grant-supported projects, except as expressly permitted in the 2 CFR Part 200.
Library Services	General library support is not allowable as a direct cost but may be included in the recipient's F&A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services).
Lobbying	Generally unallowable, in accordance with 2 CFR Part 200.450, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The recipient should obtain an advance understanding with the GMO if it intends to engage in these activities. Unallowable for State and Local governments and for-profit organizations. (Also see Public Policy Requirements and Objectives—Lobbying Prohibition, Appropriation Mandates – Lobbying – Appropriation Prohibition, and Administrative Requirements—Monitoring—Reporting concerning lobbying restrictions, the required certification, and reporting).
Maintenance and Repair Costs	Costs incurred for utilities, insurance, security, necessary maintenance, janitorial services, repair, or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life must be treated as capital expenditures (see 2 CFR

Items	Explanation of Allowable Costs
	Part 200.439 and 45 CFR Part 75.439). These costs are only allowable to the extent that they are not paid through rental or other agreements.
Materials and Supplies Costs, including Costs of Computing Devices.	1. Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable. 2. Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms should be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs. 3. Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award. 4. Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.
Meals	Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants' per diem or subsistence allowances, if any. When certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals only when consistent with terms of award. Recurring business meetings, such as staff meetings, should not be broadly considered as meetings for the primary purpose of disseminating technical information in order to justify charging meals or refreshment costs to grants.
Membership, Subscription, and Professional Activity Costs	1. Costs of the non-Federal entity's membership in business, technical, and professional organizations are allowable as an F&A cost. 2. Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable. 3. Costs of membership in any civic or community organization are allowable with prior approval by the NIH awarding IC or pass-through entity. 4. Costs of membership in any country club or social or dining club or organization are unallowable. 5. Costs of membership in organizations whose primary purpose is lobbying are unallowable. See also Lobbying. 6. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.

Items	Explanation of Allowable Costs
Moving	See Recruitment Costs, Relocation Costs, and Transportation Costs in this exhibit.
Nursery Items	Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols.
Overtime	See Salaries and Wages/Extra Service Pay (Overtime) in this exhibit.
Participant Support Costs	Only allowable when identified in specific NOFOs.
Pre-Award (Pre-Agreement) Costs	Allowable. A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: • are necessary to conduct the project, and • would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award. Pre-award costs must be charged to the initial budget period of the award, unless otherwise specified by NIH. Recipients may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the recipient's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. Pre-Award Costs are generally not applicable to training grants or fellowships. See respective sections for Individual Fellowships and Institutional Training Grants in the Ruth L. Kirschstein National Research Service Award chapter in IIB for additional information.
Professional Services Costs	1. Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the non-Federal entity, are allowable, subject to paragraphs (b) and (c) below when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Federal government. In addition, legal and related services are limited under 2 CFR Part 200.435.

Items	Explanation of Allowable Costs
	2. In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors are relevant: a. The nature and scope of the service rendered in relation to the service required. b. The necessity of contracting for the service, considering the non-Federal entity's capability in the particular area. c. The past pattern of such costs, particularly in the years prior to Federal awards. d. The impact of Federal awards on the non-Federal entity's business (i.e., what new problems have arisen). e. Whether the proportion of Federal work to the non-Federal entity's total business is such as to influence the non-Federal entity in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards. f. Whether the service can be performed more economically by direct employment rather than contracting. g. The qualifications of the individual or concern rendering the service and the customary fees charged, especially on non-federally funded activities. h. Adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation, and termination provisions). 3. In addition to the factors in paragraph (b) above, to be allowable, retainer fees must be supported by evidence of bona fide services available or rendered. Recipients, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter in IIB for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability. See Salaries and Wages/Intra-IHE Consulting.
Profit or Fee	Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an

Items	Explanation of Allowable Costs
	amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.
Proposal Costs	Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non-Federal entity. No proposal costs of past accounting periods will be allocable to the current period.
Public Relations Costs	See Advertising and Public Relations.
Publication and Printing Costs	1. Publication costs for electronic and print media, including distribution, promotion, and general handling are allowable. If these costs are not identifiable with a particular cost objective, they should be allocated as indirect costs to all benefiting activities of the non-Federal entity. 2. Page charges for professional journal publications are allowable where: a. The publications report work supported by the Federal government; and b. The charges are levied impartially on all items published by the journal, whether or not under a Federal award. If charged to the award, these costs must be charged to the final budget period of the award, unless otherwise specified by NIH c. The non-Federal entity may charge the Federal award before closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award. Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.
Rearrangement and Reconversion Costs	See Alteration and Renovation costs.

Items	Explanation of Allowable Costs
Recruiting Costs	1. Subject to paragraphs (2) and (3) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of ''help wanted'' advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non-Federal entity's standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable. 2. Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable. 3. Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part as a direct cost to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal government. See also Relocation Costs of Employees. 4. Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must: a. Be critical and necessary to conduct the project; b. Be allowable under the applicable cost principles; c. Be consistent with the non-Federal entity's cost accounting practices and non-Federal entity policy; and d. Meet the definition of ''direct cost'' as described in the applicable cost principles. Project funds may not be used for a prospective trainee's travel costs to or from the recipient organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see Travel, Relocation Costs, and Visa Costs in this exhibit).
Registration Fees (for Symposiums and Seminars)	Allowable if necessary to accomplish project objectives.

Items	Explanation of Allowable Costs
Relocation Costs of Employees	Allowable—in other than change of recipient organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the recipient's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and their family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within their control within 12 months after hire, the recipient must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the recipient organization, the personal relocation expenses of the PD/PI and others moving from the original recipient to the new recipient are not allowable charges to NIH grants (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Rental or Lease of Facilities and Equipment	Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in 2 CFR Part 200 Subpart E, are allowable only up to the amount that would be allowed had the recipient purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs. When a recipient transfers property to a third party through sale, lease, or otherwise, and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the recipient continued to own the property. Rental costs under "less-than-arms-length" leases are allowable only up to the amount that would be allowed under 2 CFR Part 200, Subpart E had title to the property been vested in the recipient. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under

Items	Explanation of Allowable Costs
	common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.
Research Patient Care	The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding IC. Routine services include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. Ancillary services are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See the Research Patient Care Costs chapter in IIB for NIH policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care costs: items of personal expense such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.
Reserve Funds	Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see Fringe Benefits/Insurance and Contingency Provisions in this exhibit).
Salaries and Wages / *IHEs — Part-time faculty*	Charges for work performed on Federal awards by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for part-time assignments.
Salaries and Wages / *IHEs — Periods outside the academic year*	1. Except as specified for teaching activity in paragraph (2) below, charges for work performed by faculty members on Federal awards during periods not included in the base salary period will be at a rate not in excess of the IBS. 2. Charges for teaching activities performed by faculty members on Federal awards during periods not included in IBS period will be based on the normal written policy of the IHE governing compensation to faculty members for teaching assignments during such periods.
Salaries and Wages / *IHEs — Sabbatical Leave Costs*	Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from their

Items	Explanation of Allowable Costs
	organization.
Salaries and Wages / *Standards for Documentation of Personnel Expenses*	Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with Federal Cost Principles and consistently applied institutional policy and practices. See 2 CFR Part 200.430(i).
Salaries and Wages	Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project. Direct salary is exclusive of fringe benefits and F&A costs. This salary guidance does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see the Consortium Agreements chapter in IIB). Salaries of federal employees with permanent appointments are unallowable except in certain circumstances (see the Grants to Federal Institutions and Payments to Federal Employees Under Grants chapter in IIB).
Salaries and Wages / *Extra Service Pay (Overtime)*	Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. Where extra service pay is a result of Intra-IHE consulting, it is subject to the reasonableness standards for Salaries and Wages above. It is allowable if all of the following conditions are met: 1. The non-Federal entity establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards. 2. The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred. This may be described in appointment letters or other documentations. 3. The supplementation amount paid is commensurate with the IBS rate of pay and the amount of additional work performed. 4. The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity. 5. The total salaries charged to Federal awards including extra service pay are subject to the Standards of Documentation as described in Salaries and Wages/IHEs.
Salaries and Wages / *Institutions of higher education (IHEs)*	Certain conditions require special consideration and possible limitations in determining allowable personnel compensation costs under Federal awards. Allowable activities: Charges to Federal awards may include reasonable amounts for activities contributing and directly related to work under an agreement, such as delivering special lectures about specific aspects of the

Items	Explanation of Allowable Costs
	ongoing activity, writing reports and articles, developing and maintaining protocols (human, animals, etc.), managing substances/chemicals, managing and securing project-specific data, coordinating research subjects, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.
Salaries and Wages / *Intra-IHE Consulting*	Intra-IHE consulting by faculty is assumed to be undertaken as an IHE obligation requiring no compensation in addition to IBS. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the faculty member is in addition to their regular responsibilities, any charges for such work representing additional compensation above IBS are allowable provided that such consulting arrangements are specifically provided for in the Federal award or approved in writing by the NIH awarding IC. Recipients, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Under no circumstances may an individual be paid as a consultant and an employee under the same NIH grant. Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be documented in writing, on a case-by-case basis, by the head of the organization (or their designee) incurring the costs – i.e., the recipient organization, consortium participant, or contractor. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.
Salaries and Wages / *Nonprofit Organizations*	For compensation to members of nonprofit organizations, trustees, directors, associates, officers, or the immediate families thereof, determination should be made that such compensation is reasonable for the actual personal services rendered rather than a distribution of earnings in excess of costs. This may include director's and executive committee member's fees, incentive awards, allowances for off-site pay, incentive pay, location allowances, hardship pay, and cost-of-living differentials.
Salaries and Wages / *Professional Activities outside of the Non-Federal Entity*	Unless an arrangement is specifically authorized by an NIH awarding IC, a non-Federal entity must follow its written non-Federal entity-wide policies and practices concerning the permissible extent of professional services that can be provided outside the non-Federal entity for non-organizational compensation. Where such non-Federal entity-wide written policies do not exist or do not adequately define the permissible extent of consulting or other non-organizational activities undertaken for extra outside pay, the Federal government may require that the effort of professional staff working on Federal awards be allocated between: 1. Non-Federal entity activities, and

Items	Explanation of Allowable Costs
	2. Non-organizational professional activities. If the NIH awarding IC considers the extent of non-organizational professional effort excessive or inconsistent with the conflicts-of-interest terms and conditions of the Federal award, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.
Salaries and Wages / *Special Considerations*	Special considerations in determining allowability of compensation will be given to any change in a non-Federal entity's compensation policy resulting in a substantial increase in its employees' level of compensation (particularly when the change was concurrent with an increase in the ratio of Federal awards to other activities) or any change in the treatment of allowability of specific types of compensation due to changes in Federal policy.
Salaries and Wages / *Unallowable Costs*	1. Costs which are unallowable under other sections of these principles must not be allowable under this section solely on the basis that they constitute personnel compensation. 2. The allowable compensation for certain employees is subject to a ceiling in accordance with statute. For the amount of the ceiling for cost reimbursement contracts, the covered compensation subject to the ceiling, the covered employees, and other relevant provisions, see 10 U.S.C. 2324(e)(1)(P), and 41 U.S.C. 1127 and 4304(a)(16). For other types of Federal awards, other statutory ceilings may apply.
Salaries and Wages /*Incentive Compensation*	Incentive compensation to employees based on cost reduction, or efficient performance, suggestion awards, safety awards, etc., is allowable to the extent that the overall compensation is determined to be reasonable and such costs are paid or accrued pursuant to an agreement entered into in good faith between the non-Federal entity and the employees before the services were rendered, or pursuant to an established plan followed by the non-Federal entity so consistently as to imply, in effect, an agreement to make such payment.
Salaries and Wages /*Overtime Premiums*	Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formally established policies of the organization consistently applied regardless of the source of funds.
Salaries and Wages /*Payments for Dual Appointments*	For investigators receiving compensation from the institution (recipient/contractor) and separately organized clinical practice plans, compensation from such sources may be included in the institutional base salary (IBS) budgeted and charged to NIH sponsored agreements if all of the following criteria are met: • Clinical practice compensation must be set by the institution. * • Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution. • Clinical practice compensation must be paid through or at the direction of the institution.

Items	Explanation of Allowable Costs
	• Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system. • The institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to NIH grants are retained and made available to Federal officials or their duly authorized representatives consistent with the requirements of 2 CFR Part 200.430. * "Set by the institution" means the recipient/contractor institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator. Further, this requires that the IBS not vary based on the specific clinical services provided by investigator within the periods for which total IBS is certified by the recipient institution.
Salaries and Wages /*Support from Multiple Grants*	See Cost Considerations—Allocation of Costs and Closely Related Work.
Selling and Marketing Costs	Costs of selling and marketing any products or services of the non-Federal entity (unless allowed under 2 CFR Part 200.421) are generally not allowable, except as direct costs, with prior approval by the NIH awarding IC when necessary for the performance of the Federal award.
Service Charge	Allowable. The costs to a user of organizational services and central facilities owned by the recipient organization, such as central laboratory, technology infrastructure fees, computer services and next generation computing/communication costs, are allowable provided that they are not covered by F&A costs. They must be based on organizational fee schedules consistently applied regardless of the source of funds.
Specialized Service Facilities	1. The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraphs (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under 2 CFR Part 200.406. 2. The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that: a. Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non- Federal entity for internal purposes, and

Items	Explanation of Allowable Costs
	b. Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s). c. Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs. d. Under some extraordinary circumstances, where it is in the best interest of the Federal government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.
Stipends	Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual's experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend supplementation, is included in Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation in IIB. Stipends are not allowable under research grants even when they appear to benefit the research project. See Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit.
Subject Costs	See Research Patient Care and Donor Costs in this exhibit.
Taxes	For nonprofit organizations and IHEs: 1. In general, taxes which the non-Federal entity is required to pay and which are paid or accrued in accordance with GAAP, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for: a. Taxes from which exemptions are available to the non-Federal entity directly or which are available to the non-Federal entity based on an exemption afforded the Federal government and, in the latter case, when the NIH awarding IC makes available the necessary exemption certificates, b. Special assessments on land which represent capital improvements, and c. Federal income taxes.

Items	Explanation of Allowable Costs
	2. Any refund of taxes, and any payment to the non-Federal entity of interest thereon, which were allowed as Federal award costs, will be credited either as a cost reduction or cash refund, as appropriate, to the Federal government. However, any interest actually paid or credited to a non-Federal entity incident to a refund of tax, interest, and penalty will be paid or credited to the Federal government only to the extent that such interest accrued over the period during which the non-Federal entity has been reimbursed by the Federal government for the taxes, interest, and penalties.
Termination or Suspension Costs	Unallowable except as follows. If a grant is terminated or suspended, the recipient may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support). NIH will allow full credit to the recipient for the Federal share of otherwise allowable costs if the obligations were properly incurred by the recipient before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension.
Trailers and Modular Units	Allowable only if considered equipment as provided below. A “trailer” is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A “modular unit” is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the recipient’s intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding IC. A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 2 CFR Part 200.439 or 200.465, as applicable.

Items	Explanation of Allowable Costs
Trainee Costs	Allowable only under predoctoral and postdoctoral training grants. (See Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs in IIB for detailed information).
Transportation Costs	Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost.
Travel	Allowable as a direct cost where such travel will provide direct benefit to the project.
Travel/*Employees*	Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs. Recipients are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements. For additional information regarding the Fly America Act and its exceptions, see Public Policy Requirements and Objectives—Fly America Act. Applicants and recipients should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of

Items	Explanation of Allowable Costs
	travelers, because they are not all required to be budgeted as travel (e.g., research subjects).
Travel/*Research Patients*	If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See also Research Patient Care in this exhibit).
Value Added Tax (VAT)	Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC. For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
Visa Costs (including short-term travel visa costs)	Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. Visa costs may also be allowable when identified in specific NOFOs or when within the scope of an approved research project. Visa renewal costs for employees is not a recruiting cost and would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud prevention and detection fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable. See also Recruiting Costs in this exhibit.

8 ADMINISTRATIVE REQUIREMENTS

8.1 CHANGES IN PROJECT AND BUDGET

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. The recipient-initiated changes that may be made under the recipient's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart IIB. In addition, individual awards may restrict recipients' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change or obligation of funds as specified later in this chapter under Requests for Prior Approval.

Recipients are required to notify NIH of developments that have a significant impact on the award-supported activities as soon as they become known. This includes significant changes to Other Support (e.g. new appointments or affiliations) that occur during the award. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this chapter.

8.1.1 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a specific term or condition of the award. Recipients must review the NoA to determine if a particular authority is withheld for a specific grant.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Recipients should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that recipient from a specific authority.

Exhibit 6. Summary of NIH Standard Terms of Award

Recipient Authorities as NIH Standard Terms of Award	Exceptions
Carryover of unobligated balances from one budget period to any subsequent period	Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NoA indicates otherwise.
Cost-related prior approval changes, including research patient care costs and equipment	The cost would result in a change of scope.
Extension of final budget period of a project period without additional NIH funds (no-cost extension)	The recipient has already exercised its one-time authority to extend the award for up to 12 months; the NIH awarding IC has previously extended the project period; and/or a project is multi-year for 5 years (i.e., the entire 5-year project period is funded by a single award).
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	The transfer would be to a foreign component or it would result in a change in scope.
Direct charge the salaries of administrative and clerical staff if conditions in 2 CFR Part 200.413 are met and the charges also meet the criteria for allowable costs described in 2 CFR Part 200.403.	
Direct charge payments of Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) 2 CFR Part 200.430. Such activities must be specifically provided for in the Federal award budget.	
Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.	

8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a specific term or condition in the NoA.

For awards under SNAP (see Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process for applicability), funds are automatically carried over to the subsequent budget period. However, the recipient will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, plus any approved carryover of funds from a prior year(s), the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30th, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

8.1.1.2 Cost-Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds

The recipient may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original completion date shown in the NoA if:

- no term of award specifically prohibits the extension,
- no additional funds are required to be obligated by the NIH awarding IC, and
- the project's originally approved scope will not change.

Such an action affirms that additional work remains to be completed on the project and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. The fact that funds remain at the completion date of the grant is not, in itself, sufficient justification for an extension without additional funds.

With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measurable level of effort.

Recipients must use the eRA Commons No-Cost Extension feature to electronically notify NIH that they are exercising their one-time authority to extend without funds the completion date of an award. This extension feature becomes available to the recipient 90 days before the project period end date. Extensions may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. An e-mail notification is automatically sent to the GMO. No further action by the recipient is required.

Notifications may not be submitted via e-mail or fax. If a no-cost extension notification is submitted late, the eRA Commons No-Cost Extension feature cannot be used. Instead, the extension notification becomes a request and that requires the approval of the IC GMO. Recipients who miss the window (or opportunity) to extend the grant in eRA Commons must submit a written prior approval request to the NIH awarding IC for consideration. (See Administrative Requirements—Prior Approval Requirements for extension requiring additional funds.)

In extending the final budget period of the project period through this process, the recipient agrees to update all required certifications and assurances, including but not limited to those pertaining to human subjects and vertebrate animals, in accordance with applicable regulations and policies. Recipients are reminded that all terms and conditions of the award apply during the extension period.

Recipients may not extend project periods that were previously extended by the NIH awarding IC. Any additional project period extension requires NIH prior approval. (See Administrative Requirements—Prior Approval Requirements for extensions requiring additional funds.)

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit or eliminate this authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

The provisions in this subsection do not apply to fellowship awards.

8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already peer reviewed programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff

The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;
2. Individuals involved can be specifically identified with the project or activity;
3. Such costs are explicitly included in the budget; and
4. The costs are not also recovered as indirect costs.

Such charges must also meet the criteria for allowable costs described in 2 CFR Part 200.403.

NIH prior approval is not required to rebudget funds for this direct cost item post-award. Prior approval is only required when additional funds are being requested for such a position.

8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs

IHEs may direct charge payments of incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) and not include them in the records described in 2 CFR Part 200.430. Such activities must be specifically provided for in the Federal award budget.

8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions.

IHEs may include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member’s base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member’s regular departmental load.

8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require NIH prior approval. NIH prior approval requirements are summarized in Exhibit 7, which is provided for guidance only. For the prior approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact. The circumstances under which prior approval is required also are summarized in the exhibit.

Recipients also should consult Subpart IIB for prior approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

Exhibit 7. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension (8.1.2.1)	All instances.
A&R (8.1.2.2)	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Addition of a Major single A&R project.
Capital expenditures (construction, land, or building acquisition) (8.1.2.3)	All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Carryover of unobligated balances (8.1.2.4)	If the NoA indicates that the recipient does not have the authority to automatically carry over unobligated balances.
Change in scope (8.1.2.5)	All instances.
Change in status of the PD/PI or senior/key personnel named in the NoA (8.1.2.6)	A significant change in the status including but not limited to withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award.
Change of recipient organization (8.1.2.7)	All instances.
Change of recipient organization status (8.1.2.8)	All instances.
Deviation from award terms and conditions (8.1.2.9)	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.
Foreign component added to a grant to a domestic or foreign organization (8.1.2.10)	All instances.
Make subawards based on fixed amounts (8.1.2.11)	All instances
Need for additional NIH funding (8.1.2.12 and 8.1.2.13)	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs (8.1.2.14)	More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the recipient's own risk.

NIH prior approval is required for	Under the following circumstances
Rebudgeting funds from trainee costs (8.1.2.15)	All instances.
Rebudgeting of funds between construction and non-construction work (8.1.2.16)	All instances.
Retention of research grant funds when CDA awarded (8.1.2.17)	All instances.

8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension

The NIH Standard Terms of Award provide the recipient the authority to extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original completion date down in the NoA. Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension. Further any late notification of the initial no-cost extension provided by the NIH Standard Terms of Award also requires prior approval.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

8.1.2.2 Alterations and Renovations

NIH prior approval is required if a recipient wishes to rebudget more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in the addition of a Major A&R project, NIH will consider the rebudgeting to be a change in scope. (See the Construction Grants chapter in IIB for documentation requirements for Major A&R projects).

8.1.2.3 Capital Expenditures

Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient without the written prior approval of the NIH awarding IC or its successor organization.

8.1.2.4 Carryover of Unobligated Balances

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is

required by the NIH awarding IC. When NIH prior approval is required, the AOR should submit a request to the GMO that includes at a minimum the following information:

- A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds. If personnel costs are requested, include a detailed breakdown of personnel costs, including base salary, salary requested and effort to be spent on the project during the extension. In general, carryover action requiring prior approval will be approved using the F&A rate that was in effect at the time the initial funds were awarded for the year to which the funds are being carried over. For example, if the carryover is approved from year -01 to year -03, the F&A rate used to calculate the revised -03 year award will be the rate used to initially calculate year -03. However, actual expenditures will still be based on the rate applicable when the cost is incurred.
- A scientific justification for the use of funds.
- The reason for the unobligated balance.

8.1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals.

- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
    - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award;
        - From non-human subjects research to research involving human subjects (exempt or non-exempt);
        - From exempt to non-exempt research involving human subjects; or
        - From "No Clinical Trial" to "Includes a Clinical Trial." Requests for this change must be submitted to a clinical trial NOFO as a competitive revision. See NIH definition of clinical trial and 2.3.5 — Types of Notices of Funding Opportunity.
    - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR Part 46 subparts B, C or D (pregnant women, human fetuses, and neonates; prisoners; or children).
    - Any change to the study protocol that would increase the risk level for subjects including physical, psychological, financial, legal or other risks. This could include the addition of a new study population that would be at higher risk from existing research procedures, the addition of new study procedures that are greater than minimal risk, any modification of existing study procedures that would increase overall risk, or the addition of a new clinical study or a new clinical trial intervention arm not originally proposed that is greater than minimal risk.
    - New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA (see Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is $200,000, any rebudgeting that would result in an increase or decrease of more than $50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.
- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a recipient desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.

- Purchase of a unit of equipment exceeding $25,000.

8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The recipient is required to submit a prior approval request to the GMO if:

- There is a significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months). Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting **Yes** in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
- There is a change from a multiple PD/PI model to a single PD/PI model.
- There is a change from a single PD/PI model to a multiple PD/PI model.
- There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

NIH must approve any alternate arrangement proposed by the recipient, including any replacement of the PD/PI or senior/key personnel named in the NoA, and the addition of any new PD/PIs.

The request for prior approval of any additional or substitute PD/PIs or Senior/Key Personnel named in the NoA, or change from a multiple PD/PI model to a single PD/PI model, must be submitted promptly, and must be accompanied by a strong scientific justification related to the scientific project, including any proposed changes in scope, the biographical sketch of any new individuals proposed and other sources of support, and any budget changes resulting from the proposed change. A new or revised Leadership Plan is required if the request is to change from a single PD/PI model to a multiple PD/PI model, or to change the number or makeup of the PD/PIs on a multiple PD/PI award. The Commons ID must be provided for any new PD/PIs.

In addition, because NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research, the request for approval should include mention as to whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (bullying, retaliation, or hostile working conditions). NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through the dedicated web form, Inform NIH About Harassment or Discrimination Concerns.. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

If the arrangements proposed by the recipient, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated. If the recipient wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to those personnel NIH designates in the NoA regardless of whether the applicant organization designates others as senior/key personnel for its own purposes.

8.1.2.7 Change of Recipient Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment). A change of recipient organization may be accomplished under most NIH grants if any of the following conditions are met:

- The original recipient has agreed to relinquish responsibility for an active project before the completion date of the approved project period. This includes any proposed change of recipient as a result of a PD/PI on a research project transferring from one organization to another organization. The project under the same PD/PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.
- A non-competing continuation award that is within an approved project period has been withheld because of the recipient's actions (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

A request for change of recipient organization should include mention as to whether the change in recipient institution is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions) involving the PD/PI. NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through a dedicated web form. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action (s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

NIH expects both the relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or research misconduct.

A change of recipient that involves the transfer of a grant to or between foreign organizations or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred.

A successor-in-interest or a name change is not considered a change of recipient (see Change in Recipient Organizational Status below).

A change of recipient organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original recipient's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

A change of recipient request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. NIH will also consider the length of time, the percentage of funds, and the amount of work remaining in the project period. A change may be made without peer review, provided the PD/PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award.

A change of recipient organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or significant delays in processing. Recipients are encouraged to discuss any potential issues with the awarding IC(s) prior to submitting a change of recipient organization request. If requesting a transfer in the middle of a budget period or at the end of the Federal fiscal year, recipients should contact the awarding IC for IC-specific guidance on the timing and preparation of the change of institution application.

A request for a change of recipient organization must be submitted to the GMO. The original institution must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement). The relinquishing statement may be submitted in paper or electronically via the eRA Commons. Final FFR Expenditure Data and a Final Invention Statement are due to NIH from the relinquishing organization no later than 120 days after the end of NIH support of the project. Final FFR Expenditure Data should not be submitted until the original institution has received a revised NoA for the relinquished grant.

The proposed new recipient institution must provide the GMO with a change of institution application which may be submitted using the PHS 398 or PHS 416-1 paper application forms, or electronically via Grants.gov using the Parent Announcement. If the original award was the result of a modular application and the recipient will submit a paper change of institution application, the modular procedures apply to the request for change of recipient. If the original award was the result of a modular application and the recipient will submit an electronic change of institution application, the recipient may submit a detailed budget or streamlined-detailed budget (as described in the NOFO).

The paper application from the proposed new recipient institution should include, at a minimum, the following:

- PHS 398 Face page
- Budget pages (current and future years). (Under awards resulting from modular applications, the application should include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs (plus applicable F&A costs) previously recommended for any budget period. For transfers in the middle of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC. For these applications, recipients will also need to include the Other Project Information and the Senior/Key Personnel components.
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel.
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- Updated "other support" page(s), if necessary.
- Resources page, including probable effect of the move on the project.
- Checklist page
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

The electronic application from the proposed recipient institution should include, at a minimum, the following:

- SF 424 (R&R) Cover Component
- SF 424 (R&R) Project Performance Site Location(s)
- SF 424 (R&R) Other Project Information:
    - Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
    - Facilities and Other Resources, including probable effect of the move on the project.
    - Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of the list in the transfer application from the new organization indicates its acceptance of title to that equipment).
- SF 424 (R&R) Senior/Key Person Profile:
    - Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel, and updated "other support" page(s) as necessary.

- Budget pages applicable for activity code (current and future years). If the budget for the original award was submitted in a modular format, use the R&R Detailed Budget form for all electronic applications. Recipients may either complete all of the fields in the R&R Detailed Budget as appropriate or complete only the costs for the PD/PI (Section A), and include the remainder of the direct costs under Section F (Other Direct Costs) Items 8-17, and Section H (Indirect Costs). (For awards resulting from modular applications, include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs previously recommended for direct costs (plus applicable F&A costs) for any budget period. For transfers during the course of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC.
- PHS 398 Research Plan
    - If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- PHS 398 Cover Page Supplement
- PHS 398 Checklist

And, as applicable:

- PHS Training Budget Form
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Form
- PHS Human Subjects and Clinical Trial Information Form
- SBIR/STTR Information

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of recipient organization by issuing a revised NoA to the original recipient reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in PMS, whichever is less.)

Concurrently, the new recipient will receive the NoA reflecting the direct cost balance reported on the relinquishing statement plus applicable F&A costs, if funds are available. If the change of recipient organization occurs on the anniversary date of the project, the NoA to the new recipient will reflect the previously committed direct cost level plus applicable F&A costs if funds are available. If the change of recipient organization occurs during the course of the budget period, the policy of the awarding IC will determine if the NoA to the new recipient will reflect the direct cost relinquished by the former recipient plus applicable F&A costs or the total costs relinquished by the former recipient. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs before the beginning date of a transfer award. The recipient may do so only if those costs are necessary to conduct the project and would not require prior approval if incurred under an awarded grant. For the purposes of pre-award costs, transfers are treated like non-competing continuation awards.

Therefore, the pre-award costs incurred are not limited to 90 days prior to the beginning date of the initial budget period of that transferred award to the new recipient organization.

8.1.2.8 Change in Recipient Organizational Status

Recipients must give NIH advance notice of the following types of change in organizational status (not a change of recipient organization as described above):

- ***Merger.*** Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.
- ***Successor-in-Interest (SII).*** Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
- ***Name Change.*** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

Advance notification is required to ensure that the recipient remains able to meet its legal and administrative obligations to NIH, and payments are not interrupted.

Recipients are encouraged to contact the GMO of the lead NIH awarding IC to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding IC ordinarily will be the IC with which the organization has the most NIH grants. NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A recipient's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current recipient (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding IC, following consultation with the GMO of that awarding IC. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the awarding IC(s) modify its (their) records to reflect the transferee as the recipient of record.
- State the effective date of the transfer.
- Provide the transferee's EIN. If EIN is new, include completed Form W-9.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance).

- Include a list of all affected NIH grants (active and pending) with the following information for each:
    - Complete grant number (e.g., 5 R01 GM 12345-04).
    - Name(s) of PD/PI(s).
    - Current budget period and project period.
    - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant), which may be submitted on paper or electronically through the eRA Commons, or may be itemized by grant number as an attachment to the letter. When an SII occurs during a budget period, the deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as reported on the relinquishing statement or the available balance in PMS, whichever is less.
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by an AOR at the transferee organization.

- Include a copy of the current negotiated F&A rate agreement for the transferee.

Recipients may choose to submit an electronic application for a successor-in-interest request to satisfy the requirement for the face page(s), confirmation of the transferee's EIN, verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance), and Relinquishing Statement. The electronic application is submitted via Grants.gov using the Parent Announcement.

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements; except for grants awarded under the SBIR/STTR programs. See Small Business Innovation Research and Small Business Technology Transfer Programs—Eligibility in IIB for additional guidance. Upon review and acceptance of this information, NIH will revise the NoA(s) to show the transferee as the recipient of record.

For name changes, the recipient's written notification to the lead NIH awarding IC must include the effective date of the change. Revised face pages are not required for name changes because name changes are reported and processed with the next award action (e.g., non-competing continuation award).

8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organization

Adding a foreign component under a grant to a domestic or foreign organization requires NIH prior approval.

8.1.2.11 Provide Subawards Based on Fixed Amounts

With NIH prior approval, a pass-through entity may provide subawards based on fixed amounts (as defined in 2 CFR Part 200.201), to which the following conditions apply:

1. The Fixed amount subaward is negotiated using the cost principles (or other pricing information) as a guide. The pass-through entity may use fixed amount subawards if the project scope has specific measurable goals and objectives and if adequate cost, historical, or unit pricing data is available to establish a fixed amount subaward based on a reasonable estimate of actual cost. Payments are based on meeting specific requirements of the subaward. Accountability is based on performance and results. Except in the case of termination before completion of the subaward, there is no governmental review of the actual costs incurred by the non-Federal entity in performance of the subaward. Some of the ways in which the fixed amount subaward may be paid include, but are not limited to:
    a. In several partial payments, the amount of each agreed upon in advance, and the "milestone" or event triggering the payment also agreed upon in advance, and set forth in the subaward;
    b. On a unit price basis, for a defined unit or units, at a defined price or prices, agreed to in advance of performance of the subaward and set forth in the subaward; or,
    c. In one payment at subaward completion.
2. A fixed amount subaward cannot be used in programs which require mandatory cost sharing or match.
3. The non-Federal entity must certify in writing to the pass-through entity at the end of the subaward that the project or activity was completed or the level of effort was expended. If the required level of activity or effort was not carried out, the amount of the subaward must be adjusted.
4. Periodic reports may be established for each fixed amount subaward.
5. Changes in principal investigator, project leader, project partner, or scope of effort must receive the prior written approval of the pass-through entity.

When considering the use of a fix amount subaward, note the distinction between a fixed-amount subaward and a fixed-rate agreement.

In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. In a fixed-rate agreement, while there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study), the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 2 CFR Part 200.201, prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement.

8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Project Period

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted, is a non-competing

supplemental application. Such requests must be submitted electronically, for both single and multi-project awards, and are not required to compete with other applications for funding. Other recipient-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications. When calculating the award for additional funds, NIH will 1) prorate funding if the requested budget is adjusted at the time of award, and 2) use the institution's current F&A rate; i.e., the rate in effect when the new funding is provided.

8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months and must be either for work that remains to be completed on the project or to permit orderly phase-out of project activities for which there will be no further NIH support. Resources must be available to continue to support the project. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. For NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period with funding.

8.1.2.14 Pre-Award Costs

See Cost Considerations—Selected Items of Cost—Pre-Award (Pre-Agreement) Costs.

8.1.2.15 Rebudgeting of Funds from Trainee Costs

The rebudgeting of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds in IIB).

8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work

Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.

8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued

Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

8.1.3 Requests for Prior Approval

All requests for NIH awarding IC prior approval must be made in writing (including submission by e-mail) to the GMO no later than 30 days before the proposed change, and signed by the AOR. If the request is e-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a subrecipient for prior approval will be addressed in writing to the recipient. The recipient will promptly review such request and shall approve or disapprove the request in writing. A recipient will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal-award to the recipient. If the revision, requested by the subrecipient would result in a change to the recipient's approved project which requires Federal prior approval, the recipient will obtain the awarding IC's approval before approving the subrecipient's request. Failure to obtain required prior approval from the appropriate awarding IC may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority. While the PD/PI signature is no longer required as part of the submission to NIH, the recipient must secure and retain such a signature for each prior approval request and make it available to NIH or other authorized DHHS or Federal officials upon request. When multiple PD/PIs are recognized for a particular grant, this requirement applies to all PD/PIs. (See Policies Affecting Applications-Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance).

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the NIH Enterprise Directory. E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever recipients contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the pass-through entity. However, the pass-through entity may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the pass-through entity must obtain that approval from NIH before giving its approval to the consortium participant.

8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as recipients abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources "research tools" may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Specific terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 2 CFR Part 200.315). The disposition of royalties and other income earned from a copyrighted work is addressed in Administrative Requirements—Management Systems and Procedures—Program Income.

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH grant must include:

1) An acknowledgment of NIH grant support such as:

"Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345]."

2) A disclaimer that says:

"The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See http://www.nih.gov/news/media_contacts.htm for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports and Administrative Requirements—Closeout—Final Reports—Final Progress Report). When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also NIH Public Access Policy below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the NIH NLM PMC, a free digital archive of full-text biomedical and life sciences journal literature. Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH, including research grant and career development awards, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, SBIR/STTR awards, and NIH intramural research studies.

Additional information can be found at: http://publicaccess.nih.gov/.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can

impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page.

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

NIH has published a set of principles and guidelines known as the NIH Research Tools Policy for funding recipients and the biomedical community. These serve as a reference for identifying an appropriate strategy for disseminating and sharing research tools. The NIH Research Tools Policy webpage explains these principles and guidelines in more detail and provides suggestions on implementation.

For recipients working with biological materials, NIH has a policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued. To learn more, read "NIH Procedures for Handling Non-election of Title to Patentable Biological Materials".

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see Administrative Requirements—Management Systems and Procedures—Program Income).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced *NIH Research Tools Policy webpage*. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

8.2.3.1 Policy for Data Management and Sharing (DMS Policy)

The NIH Policy for Data Management and Sharing (DMS Policy) applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities. A list of NIH activity codes subject to the DMS Policy is available on the NIH website, and the applicability of the DMS Policy will be specified in each NIH NOFO.

Applicants must submit a DMS Plan in each competitive grant application, and outline DMS costs in the appropriate cost categories in the budget (see NIH Application Guide for detailed instructions). DMS Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), DMS Plans should be

updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner. DMS Plans from NIH-funded or conducted research may be made publicly available and should not include proprietary or private information. Costs associated with data management and data sharing are subject to Federal cost principles for the reimbursement of actual costs that are allowable, allocable, reasonable, and consistently treated as described in NIHGPS Section 7.2 The Cost Principles.

Under the NIH DMS Policy, NIH expects researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Shared scientific data must be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

Consistent with 2 CFR 200.403 and the NIHGPS Section 7.4, budget requests must not include infrastructure costs that are included in institutional overhead (e.g., Facilities and Administrative costs) or costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research and should not be included in scientific data management and sharing budgets. Costs may not be double charged or inconsistently charged as both direct and indirect costs.

Applicants may request data management and sharing costs that are allowable and reasonable when associated with (1) Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access. (2) Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository). (3) Preserving and sharing data through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a DMS Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance. If the DMS Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

Generally, DMS Plans are not considered during peer review, unless the NOFO identifies data sharing as integral to the project. DMS Plans will undergo programmatic assessment by NIH staff following peer review. ICs may request additional information at Just-in-Time in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Once approved, the DMS Plan will become a Term and Condition of the NOA, and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions. In accordance with NIHGPS Section 8.1.1 NIH Standard Terms of Award, recipients must obtain prior approval to make changes to the previously approved DMS Plan (e.g. change in scientific direction, change in repository, or change in the timeline). All prior approval requests must be submitted in the eRA Prior Approval Module (see NIH Application Guide).

All allowable Data Management and Sharing costs in budget requests must be incurred (e.g., curation fees, data repository fees) during the performance period, even for scientific data and metadata preserved and shared beyond the award period.

Recipients are required to provide updates on the activities described in the DMS plan as part of the annual RPPR, and the IC will use this information to assess compliance with the previously approved DMS Plan.

For additional information and resources, see the NIH Scientific Data Sharing website.

8.2.3.2 Genomic Data Sharing (GDS) Policy

The NIH Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports NIH's mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health.

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of the GDS Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include GWAS, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the GDS Policy provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to describe plans for sharing genomic data in the DMS Plan submitted with the application, and not in a separate GDS Plan or at Just-in-Time, consistent with the changes described in 8.2.3.1 Policy for Data Management and Sharing. For guidance on development a DMS plan that meets the requirements of the DMS plan that meets the requirements of the GDS policy, see the NIH Scientific Data Sharing website.

Investigators who wish to use cloud computing for storage and analysis will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research.

As with data stored in institutional systems, the institution’s signing official, Program Director/Principal Investigator, IT Director, and any other personnel approved by NIH to access the data are responsible for ensuring the protection of the data. The institution, not the cloud service provider, assumes responsibility for any failure in the oversight of using cloud computing services for controlled-access data.

The NIH Security Best Practices for Controlled Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy has been updated to include best practices for cloud computing. The Model Data Use Certification has also been updated and is available at http://gds.nih.gov/pdf/Model_DUC.pdf.

8.2.3.3 Sharing Model Organisms

All applications, regardless of amount requested, where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible.

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, Arabidopsis, fruit fly, zebrafish, and frog. Research resources to be shared include, but are not limited to, genetically modified organisms, mutant organisms, sperm, embryos, vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, genetic and phenotypic data for all mutant strains.

For additional information on this policy, see the NIH Scientific Data Sharing Model Organism Sharing Policy website.

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations regardless of size and all non-profit entities. (See 2 CFR Part 200 and 37 CFR Part 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical application while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR Part 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also Section 8.5.2 for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 CFR Part 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the Division of Extramural Inventions and Technology Resources, OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 CFR Part 401 *et seq* suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Invention Disclosure	**The term "Subject Invention"** means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an **Initial Patent Application**. **Statutory Period** is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102 (b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year **Statutory Period** wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the **Initial Patent Application** the license applies to all subsequent patent applications linked in the patent family.	When the **Initial Patent Application** is filed.	401.14(f)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Government Support Clause	The recipient must include, within the specification of all United States patent applications and any patent issuing thereon covering a Subject Invention, the following statement, "This invention was made with government support under (grant number, including the two-letter institute code and six-digit serial number, e.g., CA012345) awarded by the National Institutes of Health. The government has certain rights in the invention."	Must be included within the specifications of any United States patent applications and any patent(s) issuing thereon covering a Subject Invention.	401.14(f)(4)
Patent Applications and Issued Patents	The recipient must inform NIH of the filing date of its **Initial Patent Application**, the **Initial Patent Application** number and title and all subsequently filed patent applications. **Initial Patent Application** is defined as the first provisional or nonprovisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(2) and (3), respectively, the first international application filed under the Patent Cooperation Treaty as defined in 37 CFR Part 1.9(b) that designates the United States, or the first application for a Plan Variety Protection certificate, as applicable, a non-provisional U.S. national application for patent as defined in 37 CFR Part 1.9(a)(3).	Within 1 year after election of title, or, if earlier, prior to the end of any Statutory Period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use, unless there is an extension of time granted by NIH.	401.14(c)(3) 401.14.(f)(6) 401.2(n)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Notification to NIH to Not to Continue Prosecution	Notify NIH of any decision to: not to continue the prosecution of a non-provisional patent application; not to pay a maintenance, annuity or renewal fee; not to defend in a reexamination or opposition proceeding on a patent, in any country; to request, be a part to, or take action in a trial proceeding before the Patent Trial and Appeals Board of the U.S. Patent and Trademark Office including but not limited to post-grant review, review of a business method patent, *inter partes* review, and deviation proceeding; or to request, be a part to, or take action in a non-trial submission of art or information at the U.S. Patent and Trademark Office, including but not limited to a pre-issuance submission, a post-issuance submission, and supplemental examination.	Notify NIH no less than 60 days prior to taking any action defined under "Action Required."	401.14(f)(3)
Assignment of Rights to Third Party	If the recipient is a non-profit organization, it must request NIH prior approval to assign a Subject Invention or U.S. patent rights to any third party, including the inventor(s). Recipients that are for-profit entities (including small businesses) do not need to request approval for the assignment of a Subject Invention or U.S. patent rights to any third party.	Recipient must submit a Third-Party Waiver Request or an Inventor Waiver Request and must have NIH approval before any rights of the recipient are transferred or assigned.	401.10 401.14(k)(1)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Preference for United States Industry	Recipient cannot grant to any person, unless approved by NIH in advance, the exclusive right to use or sell any Subject Invention in the United States unless any such product embodying the Subject Invention or produced through the use of the Subject Invention is manufactured substantially in the United States.	For a waiver of this compliance requirement, a request is required to NIH providing specific details and reasons why the Subject Invention cannot be substantially manufactured in the United States.	401.14(i)
Issued Patent	Recipient must notify NIH of the date a patent is issued, patent number, and the expiration date of the issued patent.	When patent is issued.	401.5(f)(2)
Extension of Time to Disclose a Subject Invention	The recipient may request for NIH's approval for an extension of time to disclose a Subject Invention.	Not less than 30 days in advance of the 60-day disclosure reporting deadline.	401.14(c)(5)
Extension of Time to Elect Title to a Subject Invention	Recipient may request with justification, NIH's approval of a request for an extension of up to 2 years to elect title to a Subject Invention.	As needed before the expiration of the time allowed.	401.14(c)(5)
Extension of Time to File a Patent Application	The recipient may request, subject to NIH's approval, an extension time up to 1 year to file a patent application. The request must include details of why an extension is needed.	As needed before the expiration of the time allowed.	401.14(c)(5)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. *(All Compliance Actions are to be Submitted to NIH through iEdison)*	37 CFR Part 401 Reference
Extension of Time to File a Non-provisional Patent Application following the Filing of a Provisional Application as the Initial Patent Application	When a recipient requests an extension of time for filing a non-provisional application, after filing a provisional application as an **Initial Patent Application**, a 1-year extension will be granted unless NIH notifies the recipient within 60 days of receiving the request. Recipient must submit this request citing an extension of time pursuant to 401.14(c)(5). No additional details for the request are required.	As needed before the expiration of the time allowed.	401.14(c)(5)
Invention Utilization Report	The recipient must submit an annual utilization report with information about the status of commercialization of any Subject Invention for which title has been elected.	Annually, based on the fiscal year of the recipient.	401.14(h)
Annual Invention Statement	The recipient must indicate any inventions made during the previous budget period in Section C of the Research Performance Progress Report (RPPR).	Part of all competing applications and non-competing continuation progress reports.	SF424, (R&R) PHS 2590, RPPR
Final Invention Statement and Certification	The recipient must submit to the NIH awarding IC CGMO through the eRA Closeout Module a summary of all inventions made during the entire term of each grant award.	Within 120 days after the project period (competitive segment) ends.	401.14(f)(5)

8.2.5 Interim Research Products

Interim Research Products are complete, public research products that are not final. A common form is the preprint, which is a complete and public draft of a scientific document. Interim research products are effective ways for NIH funded scientists to speed dissemination, establish priority, obtain feedback, and reduce bias. They may also be cited in applications for NIH funding.

NIH intends to maximize impact of interim research products that are developed with NIH funds. Therefore, NIH expects recipients to ensure a high level of public access to NIH supported interim products.

To facilitate text mining and other analysis of these products as data, NIH expects standardized terms of use. NIH also expects recipients will adhere to other norms of responsible scientific communication.

Specifically, to claim an interim research product as a product of an NIH award, NIH expects that the recipient will:

- Make the product publicly available. To maximize the impact of an interim research product, NIH strongly encouragesrecipients to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
  - Acknowledge NIH funding in accordance with NIH GPS Section 8.2.1
  - Clearly state that the work is not peer-reviewed
  - Declare any competing interests, as an author would do for any journal article

8.3 MANAGEMENT SYSTEMS AND PROCEDURES

Recipient organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Recipients may use their existing systems to manage NIH grant funds and activities as long as they are consistently applied regardless of the source of funds and meet the standards and requirements set forth in 2 CFR Part 200 and the NIHGPS. NIH may review the adequacy of those systems and may take appropriate action, as necessary, to protect the Federal government's interests, including, but not limited to, the use of specific terms and conditions. NIH also will oversee the recipient's systems as part of its routine post-award monitoring. The recipient's systems also are subject to audit (see Administrative Requirements—Monitoring—Audit).

NIH seeks to foster within recipient organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include a clear delineation of the roles and responsibilities of the organization's staff, both programmatic and administrative; written policies and procedures; training; performance assessment; administrative simplifications; information sharing; management controls and other internal controls.

Recipient organizations must establish and maintain effective internal controls to provide reasonable assurance that they are in compliance with Federal statutes, regulations, and terms and conditions of award (2 CFR 200.303(a) and (b)). They must evaluate and monitor their compliance with statutes, regulations, and terms and conditions (2 CFR 200.303(c)), and they must take prompt action when instances of noncompliance are identified (2 CFR 200.303(d)).

Recipient organizations' internal controls should be in compliance with guidance in "Standards for Control in the Federal Government." (2 CFR 200.303(a)). Thus, recipient organizations are expected to establish codes of conduct which define expectations of integrity and ethical values and criteria of competence of personnel involved in the work supported by NIH grant funds. Codes of conduct should articulate expectations to assure compliance with terms and conditions of award, including but not limited to, providing true, complete, and accurate information on application documents (2.3.7.6); assuring work environments are free of discriminatory harassment and are safe and conducive to high-quality work (4); and meeting applicable public policy requirements (4.1).

8.3.1 Financial Management System Standards

Recipients are required to meet the standards and requirements for financial management systems set forth or referenced in 2 CFR Part 200.302 as applicable. The standards and requirements for a financial

management system are essential to the grant relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Recipients must have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds. Recipients must notify NIH when problems are identified.

A recipient's failure to establish adequate control systems constitutes a material violation of the terms of the award. Under these circumstances, NIH may include specific conditions on awards or take any of the range of actions specified in Administrative Requirements—Enforcement Actions, as necessary and appropriate.

8.3.2 Program Income

Program income is gross income—earned by a recipient, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; registration fees for grant-supported conferences, and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) The requirements for accountability for these various types of income under NIH grants are specified in this subsection. Accountability refers to whether NIH will specify how the income is to be used and whether the income needs to be reported to NIH and for what length of time. Unless otherwise specified in the terms and conditions of the award, NIH recipients are not accountable for program income accrued after the period of grant support.

NIH applies the additive alternative to all recipients, including for-profit entities, unless there is a concern with the recipient or activity and NIH uses specific terms and conditions, or the program requires a different program income alternative. NIH may require a different use of program income if a recipient has deficient systems; if the PD/PI has a history of frequent, large annual unobligated balances on previous grants; or if the PD/PI has requested multiple extensions of the final budget period of the project period. Regardless of the alternative applied, program income may be used only for allowable costs in accordance with the applicable cost principles and the terms and conditions of the award. Each NoA will indicate the allowable treatment of program income. Program income alternatives and their usage are noted below in Exhibit 9.

Consortium agreements and contracts under grants are subject to the terms of the agreement or contract with regard to the income generated by the activities, but the terms specified by the recipient must be consistent with the requirements of the grant award. Program income must be reported by the recipient as discussed in this subsection.

8.3.2.1 Reporting Program Income

The amount of program income earned and the amount expended must be reported on the appropriate annual financial report, currently the FFR. Any costs associated with the generation of the gross amount of program income that are not charged to the grant should be deducted from the gross program income earned, and the net program income should be the amount reported. Program income must be reported in the Program Income section of the FFR (lines 10 L – O). (See Administrative Requirements—

Monitoring—Reporting—Financial Reporting.) For awards under SNAP, the amount of program income earned must be reported in the non-competing continuation progress report.

Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

When applicable, income earned from the sale of equipment must be reported on the FFR for the period in which the proceeds are received in accordance with the reporting requirements for the program income alternative specified. Amounts due NIH for unused supplies must be reflected as a credit to the grant on the FFR using line 10 m.

Reporting requirements for accountable income accrued after grant support ends will be specified in the NoA.

Exhibit 9. Use and Applicability of Program Income Alternatives

Program income alternative	Use of program income	Applicability
Additive Alternative	Added to funds committed to the project or program and used to further eligible project or program objectives.	Applies to all NIH awards unless there is a concern with the recipient or activity or the program requires a different alternative.
Deductive Alternative	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based.	Available for use by NIH programs on an exception basis.
Combination Alternative	Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.	Available for use by NIH programs on an exception basis.
Matching Alternative	Used to satisfy all or part of the non-Federal share of a project or program.	Available for use by NIH programs that require matching.

8.3.2.2 Sale of Real Property, Equipment, and Supplies

The requirements that apply to the sale of real property are addressed in the Construction Grants chapter. For equipment and supplies purchased under NIH grants for basic or applied research by non-profit institutions of higher education or non-profit organizations whose principal purpose is the conduct of scientific research, the recipient is exempt from any requirement to account to NIH for proceeds from the sale of the equipment or supplies; however, NIH has certain rights with respect to such property as specified in Administrative Requirements—Management Systems and Procedures—Property Management System Standards.

All other types of grants and recipients are subject to the requirements specified in 2 CFR Part 200.313 if title to the equipment vests in the recipient rather than in NIH. If the grant-supported project or program for which equipment was acquired is still receiving NIH funding at the time of sale, the recipient must credit the NIH share of the proceeds to the grant and use that amount under the deductive alternative for program income. If the recipient is no longer receiving NIH grant support, the amount due should be paid in accordance with instructions from NIH. These grants and recipients also are subject to the

requirements in 2 CFR Part 200.314 with respect to the use or sale of unused supplies. If the recipient retains the supplies for use on other than federally sponsored activities, an amount is due NIH as if they were sold.

8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH recipients do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include specific terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

However, the regulations implementing the Bayh-Dole Act (37 CFR Part 401.14(h)) require reporting of income resulting from NIH-funded inventions and patents. Specifically, as part of the annual invention utilization report, recipients must report income generated by all subject inventions to which title has been elected and by inventions such as research tools that have been licensed but not patented (see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and Administrative Requirements—Monitoring—Reporting).

8.3.3 Property Management System Standards

Generally, recipients may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH grant funds, provided they observe the regulatory requirements in 2 CFR Parts 200.310 through 200.316, as applicable, and the following. State governments will use, manage, and dispose of equipment acquired under a grant in accordance with state laws and procedures as specified in 45 CFR Part 92.32.

The dollar threshold for determining the applicability of several of the requirements in those regulations is based on the unit acquisition cost of an item of equipment. As defined in 2 CFR Part 200.1 , the acquisition cost of an item of equipment to the recipient includes necessary modifications and attachments that make it usable for the purpose for which it was acquired or fabricated. When such accessories or attachments are acquired separately and serve to replace, enhance, supplement, or otherwise modify the equipment's capacity and they individually meet the definition of equipment (see Glossary in Part I), any required NIH prior approval for equipment must be observed for each item. However, the aggregate acquisition cost of an operating piece of equipment will be used to determine the applicable provisions of 2 CFR Part 200.313. If property is fabricated from individual component parts, each component must itself be classified as equipment if it meets the definition of equipment. In this case, the aggregate acquisition cost of the resulting piece of equipment will determine the appropriate accountability requirements in 2 CFR Part 200.313 .

Recipients are required to be prudent in the acquisition of property under a grant-supported project. It is the recipient's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization. If prior approval is required for the acquisition, the recipient must ensure that appropriate approval is obtained in advance of the acquisition. The recipient also must follow appropriate procurement procedures in acquiring property as specified in Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements.

Recipients of NIH grants other than Federal institutions cannot be authorized to use Federal supply sources.

8.3.3.1 Real Property

See Construction Grants—Real Property Management Standards in IIB for requirements that apply to the acquisition, use, and disposition of real property. Fixed equipment that is part of a construction grant is subject to those requirements.

8.3.3.2 Equipment and Supplies

In general, title to equipment and supplies acquired by a recipient with NIH funds vests in the recipient upon acquisition, subject to property management requirements of 2 CFR Parts 200.310, 2 CFR Part 200.316. Limited exceptions to these general rules are States, which may use, manage, and dispose of equipment acquired under a grant in accordance with State laws and procedures, and certain research grant recipients with exempt property (see 2 CFR Part 200.317). These requirements do not apply to equipment for which only depreciation or use allowances are charged, donated equipment, or equipment acquired primarily for sale or rental rather than for use.

8.3.3.2.1 Exempt Property

Under the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, NIH may permit non-profit institutions of higher education and non-profit organizations whose primary purpose is the conduct of scientific research to obtain title to equipment and supplies acquired under grants for support of basic or applied scientific research without further obligation to the Federal government. However, there is one exception: NIH has the right to require transfer of title to equipment with an acquisition cost of $5,000 or more to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 2 CFR Part 200.312. NIH may exercise this right within 120 days of the completion or termination of an award or within 120 days of receipt of an inventory, as provided in 2 CFR Part 200.313, whichever is later.

8.3.3.2.2 Nonexempt Property

All other equipment and supplies acquired under all other NIH grant-supported projects by any other type of recipient are subject to the full range of acquisition, use, management, and disposition requirements of 2 CFR Part 200.313 and 2 CFR Part 200.314. Property acquired or used under an NIH grant-supported project, including any federally owned property, also is subject to the requirements for internal control specified in 2 CFR Part 200.303. Pursuant to 2 CFR Part .316, equipment (and intangible property and debt instruments) acquired with, or improved with, NIH funds must not be encumbered without NIH approval.

The recipient's management system for equipment must meet the requirements of 2 CFR Part 2.313, which include the following:

- Records that adequately identify (according to the criteria specified in the regulations) items of equipment owned or held by the recipient and state the current location of each item.
- A physical inventory of the equipment, at least once every 2 years, to verify that the items in the records exist and either are usable and needed or are surplus (a statistical sampling basis is acceptable).
- Control procedures and safeguards to prevent loss, damage, and theft.
- Adequate maintenance procedures to keep the equipment in good condition.
- Proper sales procedures when the recipient is authorized to sell the equipment.

For items of equipment having a unit acquisition cost of $5,000 or more, NIH has the right to require transfer title to the equipment to the Federal government or to an eligible third party named by the NIH awarding IC under the conditions specified in 2 CFR Part 200.313. Such transfer shall be subject to the following standards: (1) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing. (2) The awarding IC may require submission of a final inventory that lists all equipment acquired with NIH funds and federally-owned equipment. (3) If the awarding IC fails to issue disposition instructions within 120 calendar days after receipt of the inventory or if so instructed, the recipient shall sell the equipment and reimburse the HHS awarding agency an amount computed by applying to the sales proceeds the percentage of HHS share in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the NIH share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses. If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the awarding IC an amount which is computed by applying the percentage of the recipient's share in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred. If the recipient is instructed to otherwise dispose of the equipment, the recipient will be reimbursed by the HHS awarding agency for such costs incurred in its disposition. If the recipient's project or program for which or under which the equipment was acquired is still receiving support from the same HHS program, and if the HHS awarding agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise the net amount must be remitted to the HHS awarding agency by check. This right applies to nonexempt property acquired by all types of recipients, including Federal institutions, under all types of grants under the stipulated conditions.

If there is a residual inventory of unused supplies exceeding $5,000 in aggregate fair market value upon termination or completion of the grant and if the supplies are not needed for other federally sponsored programs or projects, the recipient may either retain them for use on other than federally sponsored activities or sell them, but, in either case, the recipient must compensate the NIH awarding IC for its share as a credit to the grant.

Recipients of NIH grants must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless the terms and conditions of the award provide otherwise.

8.3.3.2.3 Revocable License

As permitted under Federal property management statutes and regulations and NIH property management policies, federally owned tangible personal property may be made available to recipients under a revocable license agreement. The revocable license agreement between NIH and the recipient provides for the transfer of the equipment for the period of grant support under the following conditions:

- Title to the property remains with the Federal government.
- NIH reserves the right to require the property to be returned to the Federal government should it be determined to be in the best interests of the Federal government to do so.
- The use to which the recipient puts the property does not permanently damage it for Federal government use.
- The property is controlled and maintained in accordance with the requirements of 48 CFR Part 45.5 (the FAR).

8.3.4 Procurement System Standards and Requirements

8.3.4.1 General

Recipients may acquire a variety of goods or services in connection with a grant-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. States may follow the same policies and procedures they use for procurements from non-Federal funds and ensure that every purchase order or other contract includes any clauses required by 2 CFR Part 200.327. All other recipients must follow the requirements in 2 CFR Part 200.317 through 200.327 for the purchase of goods or services through contracts under grants. The requirements for third-party activities involving programmatic work are addressed under Consortium Agreements chapter in IIB.

A contract under a grant must be a written agreement between the recipient and the third party. The contract must, as appropriate, state the activities to be performed; the time schedule; the policies and requirements that apply to the contractor, including those required by 2 CFR Part 200, Appendix II — Contract Provisions for Non-Federal Entity Contracts Under Federal Awards and other terms and conditions of the grant (these may be incorporated by reference where feasible); the maximum amount of money for which the recipient may become liable to the third party under the agreement; and the cost principles to be used in determining allowable costs in the case of cost-type contracts. The contract must not affect the recipient's overall responsibility for the direction of the project and accountability to the Federal government. Therefore, the agreement must reserve sufficient rights and control to the recipient to enable it to fulfill its responsibilities.

When a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The NIH awarding IC has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support.
- The recipient has a legal commitment to continue the contract for its full term.

However, costs will be allowable only to the extent that they are for services provided during the period of NIH support. To limit liability if continued NIH funding is not forthcoming, it is recommended that recipients insert a clause in such contracts of $100,000 or less stipulating that payment beyond the end of the current budget period is contingent on continued Federal funding. The contract provisions prescribed by 2 CFR Part 200, Appendix II — Contract Provisions for Non-Federal Entity Contracts Under Federal Awards, paragraph B specify termination provisions for contracts in excess of $100,000.

8.3.4.2 Approval Requirements

The procurement standards in 2 CFR Part 200.325 allow NIH to require approval of specific procurement transactions under the following circumstances (and provide a mechanism for governmental recipients to be exempt from this type of review):

- A recipient's procurement procedures or operations do not comply with the procurement standards required by those regulations.

- The procurement is expected to exceed the "simplified acquisition threshold" (currently $250,000 per OMB memo M-18-18) (formerly the "small purchase threshold") established by the Federal Property and Administrative Services Act, as amended, and is to be awarded without competition or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the simplified acquisition threshold specifies a "brand name" product.
- A proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When NIH prior approval is required, the recipient must make available sufficient information to enable review. This may include, at NIH discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the applicant or recipient or may be conditioned on the receipt of additional information. Any resulting NIH approval does not constitute a legal endorsement of the business arrangement by the Federal government nor does such approval establish NIH as a party to the contract or any of its provisions.

8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises

Recipients must make positive efforts to use small businesses, minority-owned firms, and women's business enterprises as sources of goods and services whenever possible. Recipients should take the steps outlined in the applicable administrative requirements (2 CFR Part 200.321) to implement this policy.

8.3.4.4 Domestic Preferences for Procurements

As appropriate and to the extent consistent with law, the non-Federal entity should, to the greatest extent practicable under a Federal award provide a preference for the purchase, acquisition, or use of goods, products, or materials produced in the United States (including but not limited to iron, aluminum, steel, cement, and other manufactured products). The requirements of this section must be included in all subawards including all contracts and purchase orders for work or products under this award. See 2 CFR Part 200.322.

8.4 MONITORING

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH awarding ICs monitor their grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to NIH. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the recipient at the time of award.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the grant is administratively closed out and NIH is no longer providing active grant support (see Administrative Requirements—Closeout).

8.4.1 Reporting

NIH requires that recipients periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Recipients also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and closeout documents (final grant progress reports and final invention statements and certifications). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to NIH (see Financial Reports below) through PMS unless otherwise indicated in the award's terms and conditions.

Recipients are allowed a specified period of time to submit required financial and final progress reports (see 2 CFR 200.328 and 2 CFR Part 200.329, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

8.4.1.1 Non-Competing Continuation Progress Reports

Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The Research Performance Progress Report (RPPR) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information.

NIH requires the use of the RPPR for all Type 5 progress reports, including accessing the Human Subjects System link in the RPPR, if applicable, that will allow reporting of inclusion enrollment data.

Recipients should routinely query and review the NIH eRA website for a list of pending grant progress reports and due dates. Late submission of a grant progress report will result in delaying the issuance and funding of the non-competing continuation award and may result in a reduced award amount.

Recipients also have an obligation to submit a complete and accurate progress report. NIH program or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information will result in a delayed award. Incomplete or inadequate progress reports may result in a delay of continued support.

The progress report for the final budget period of a competitive segment for which a competing continuation application is submitted will be part of that application; however, if an award is not made or the recipient does not submit an application for continued support, a final RPPR is required (see Final Research Performance Progress Report).

The NIH awarding IC will specify the requirements for progress reporting under construction grants or grants supporting both construction activities, including acquisition or modernization, major alteration and renovation, and non-construction activities.

8.4.1.1.1 Requirement for Commons ID

For progress reports using the RPPR, the Commons ID requirement is part of the Participants Section and is required for the PD/PI(s) and those who worked on the project in a postdoctoral role. This could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

For undergraduate and graduate students supported on a particular research grant, a Commons ID is required. Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now. For graduate students, this could include project roles of graduate research assistant or graduate student.

When an individual is assigned the Undergraduate, Graduate Student, and/or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

8.4.1.1.2 Expectation for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers

In an effort to assist graduate students and post-doctoral researchers in achieving their career goals and become contributing members of the biomedical workforce, NIH encourages recipients to develop an institutional policy requiring that an Individual Development Plan (IDP) be implemented for every graduate student and postdoctoral researcher supported by any NIH grant and reportable on the progress report, regardless of the type of NIH grant that is used for support. This is an expectation that should be broadly implemented by institutions for all graduate students and postdoctoral researchers supported by NIH. The actual reporting of the implementation of this expectation is in the RPPR; recipients must report in RPPR *Section B. Accomplishments*, Question B.4 the use of the IDP for graduate students and/or postdoctoral researchers included in RPPR *Section D*. Participants or on a Statement of Appointment Form (PHS 2271). Do not include the actual IDP; instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

8.4.1.2 Streamlined Non-Competing Award Process

SNAP includes a number of provisions that modify annual progress reports, NoAs, and financial reports.

The NoA will specify whether an award is subject to SNAP. Awards routinely included in SNAP are “K” awards and “R” awards, except R35. Awards excluded from SNAP are those that generally do not have the authority to automatically carry over unobligated balances (centers; cooperative agreements, Kirschstein-NRSA institutional research training grants, non-Fast Track Phase I SBIR and STTR awards), clinical trials (regardless of activity code), P01, R35, and awards to individuals. However, these grants can be included in SNAP on a grant-specific basis. In addition, specific awards may be excluded from SNAP if:

- they require close project monitoring or technical assistance, e.g., high-risk recipients, certain large individual or multi-project grants, or grants with significant unobligated balances, or
- the recipient has a consistent pattern of failure to adhere to appropriate reporting or notification deadlines.

8.4.1.2.1 Modified Annual Progress Reports

While a modified, streamlined, progress report is still a feature of grants awarded under the SNAP authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.

8.4.1.2.2 Modified NoAs

Under SNAP, the GMO negotiates the direct costs for the entire competitive segment at the time of the competing award or, in the case of modular awards, determines the applicable number of modules for each budget period within the competitive segment. This eliminates the need for annual budget submissions and any negotiations, and reduces the information NIH requires to review, approve, and monitor non-competing continuation awards. SNAP NoAs are issued with only total direct and F&A costs awarded for the budget period. While direct costs categorical breakdowns are not awarded, recipients are required to allocate and account for costs by category in accordance with applicable cost principles. Future year commitments on SNAP awards reflect total cost commitments (direct plus F&A costs).

8.4.1.2.3 Modified Financial Reporting Requirements

For awards under SNAP, an FFR is required only at the end of a competitive segment rather than annually. The FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

8.4.1.2.4 Submitting SNAP Progress Reports

All SNAP progress reports are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). If the 15th falls on a weekend or Federal holiday, the due date is automatically extended to the next business day. Paper submissions are not acceptable, will not be used for consideration for funding, and will not become part of the official file. If a paper SNAP progress report is submitted, recipients will be required to resubmit the information electronically.

The RPPR module in the eRA Commons allows recipients to electronically prepare and submit progress reports and supporting documentation. The RPPR module provides the user with dedicated screens to collect the required progress report information, including appropriate uploads for text documents. Data submitted through RPPR for Performance Sites and Participants is retained in the system to assist the recipient in completion of future progress reports.

The RPPR may be routed to authorizing officials at the applicant institution for review and approval prior to submission to NIH. For SNAP awards, the RPPR module provides recipients with the option to delegate to the PD/PI the authority to submit the progress report directly to NIH. This optional authority is managed on a PD/PI basis in the eRA Commons; such authority can be rescinded at any time.

Guidance on RPPR submission is documented in the RPPR Instruction Guide.

8.4.1.3 Progress Reports for Multiyear Funded Awards

A limited number of NIH grant awards are multi-year funded, i.e., not funded in budget years but funded in full at the start of the project period from a single fiscal year appropriation. The project period and the budget period are the same in a multi-year funded (MYF) award and are longer than one year. Progress reports for MYF awards are due annually on or before the anniversary of the budget/project period start date of the award. A progress report is not required if the award is in a no-cost extension period unless specifically required by the IC. The reporting period for a MYF progress report is the calendar year preceding the anniversary date of the award. For example, if an award is made on 04/01/2021, the MYF progress report is due on or before 04/01/2022, and should report on the activities performed under the award between 04/01/2021 and 03/31/2022. For the subsequent year the MYF progress report will be due 04/01/2023, and should report on the activities performed under the award between 04/01/2022 and 03/31/2023. Information on the content of a MYF progress report and instructions on how to submit the report through the eRA Commons are posted at http://grants.nih.gov/grants/policy/myf.htm and http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. The multi-year research performance progress report (MYRPPR) link to upload the report will be available two months before the anniversary date of the award, on the eRA Commons Status search page in the folder "List of Applications/Grants" in the "Action" column. Progress reports for MYF awards must be completed by the PD/PI, and then submitted by a Signing Official (SO) or a PD/PI with delegated authority from the SO to submit a progress report. Information about SO delegation of authority to a PD/PI to submit a progress report appears in the eRA Commons User Guide under Section 10.2 Delegations..

8.4.1.4 Final Research Performance Progress Report (F-RPPR)

The F-RPPR has replaced the Final Progress Report for closeout. NIH is no longer accepting Final Progress Reports. Generally, the F-RPPR format is the same as the current annual RPPR. As part of the F-RPPR recipients will be required to report on Project Outcomes. This section will be made publicly available, allowing recipients the opportunity to provide the general public with a concise summary of the cumulative outcome or findings of the project (analogous to the Project Summary/Abstract section of the competing application).

NIH will not maintain its previous Type 2 policy which stated that "whether funded or not" the progress report contained in the Type 2 application may serve in lieu of a separate final progress report. NIH now requires that organizations submit an Interim-RPPR while their Type 2 is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's F-RPPR.

See the F-RPPR Instructions for more information. Recipients should also review the information found in Final Research Performance Progress Report.

8.4.1.5 Financial Reports

Beginning April 1, 2022, recipients are no longer required to submit quarterly cash transaction reports 30 days after the end of each calendar quarter. Instead, PMS will pre-populate the cash transaction section (lines 10a through 10c) of the FFR using recipient real-time cash advance information from PMS, and adjust recipient-reported disbursements to equal cash advance drawdowns on all non-closed sub-accounts. Recipients will be required to certify at the time of each drawdown whether the cash drawdown request is for reimbursement of actual expenditures or is an advance for immediate disbursement; recipients must assert that award funds are used in compliance with all award conditions and federal statutory requirements.

8.4.1.5.1 Cash Transaction Reports

The FFR has a dedicated section to document Federal cash receipts and disbursements. For all recipients this information is pre-populated by PMS using recipient real-time cash expenses information from PMS, and adjust recipient-reported disbursements to equal cash advance drawdowns on all non-closed sub-accounts (PMS type P).

8.4.1.5.2 Financial Expenditure Reports

Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the recipient organization. NIH requires all financial expenditure reports to be submitted using the Payment Management System. This includes all initial FFRs being prepared for submission and any revised FFRs being submitted or re-submitted to NIH. The eRA Commons and Payment Management systems allows participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH through PMS. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted the FFR Reconciliation and Financial Closeout Support Center (FFR-C) within the Office of Policy for Extramural Research Administration (OPERA).. NIH IC grants management staff also review these expenditure reports.

Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date.

In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR (see Administrative Requirements—Closeout).

Before submitting FFRs to NIH, recipients must ensure that the information submitted is accurate, complete, and consistent with the recipient's accounting system. When submitting the FFR through the Payment Management System, as applicable, the AOR or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government. Filing a false claim may result in the imposition of civil or criminal penalties.

8.4.1.5.3 Revised Financial Reports and Expenditures

Revisions for F&A Changes. Each Federal Financial Report submitted by the recipient shall reflect the proper amount of F&A costs applicable to the grant period. If a provisional or an earlier period's permanent rate is used in the report, a subsequent adjustment to the FFR is necessary if a lower permanent rate(s) applicable to the grant is established, except for Institutions of Higher Education (IHEs) subject to 2 CFR 200.

Revised Expenditure Reports. NIH requires all financial expenditure reports (domestic and foreign) to be submitted using the Payment Management System. This includes the initial FFR and any FFR

revisions being submitted or re-submitted to NIH. In some cases the recipient may have to revise or amend a previously submitted annual or final FFR. When the revision results in a balance of $20,000 or greater due to NIH, the recipient must submit a revised report whenever the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. All refunds under $20,000 on closed PMS documents should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts. PMS refund instructions may be found at https://pms.psc.gov/grant-recipients/returning-funds-interest.html. Revised expenditure reports representing additional expenditures by the recipient that were not reported to NIH within the 90-day time frame may be submitted electronically with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the recipient to preclude similar situations in the future. This should be done as promptly as possible, but no later than one year from the due date of the original report for annual FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date).

8.4.1.5.4 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. (See Administrative Requirements—Changes in Project and Budget for NIH approval authorities for unobligated balances.) Using the principle of "first in-first out," unobligated funds carried over are expected to be used before newly awarded funds.

Upon receipt of the annual FFR for awards other than those with authority for the automatic carryover of unobligated balances, the GMO will compare the total of any unobligated balance shown and the funds awarded for the current budget period with the NIH share of the approved budget for the current budget period. If the funds available exceed the NIH share of the approved budget for the current budget period, the GMO may select one of the following options:

- In response to a written request from the recipient, revise the current NoA to authorize the recipient to spend the excess funds for additional approved purposes.
- Offset the current award or a subsequent award by an amount representing some or all of the excess.

8.4.1.5.5 Recipient Reporting of Subrecipient Data and Executive Compensation Information for Federal Funding Accountability and Transparency Act (FFATA)

A component of Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires most recipients of new Federal funds to report on subawards/subcontracts/consortiums equal to or greater than $30,000. This includes awards that are initially below $30,000 but subsequent grant modifications result in an award equal to or greater than $30,000.

The FFATA Subaward Reporting System (FSRS) tool can be accessed directly at www.fsrs.gov, and will serve as the collection tool for subaward data which will ultimately be distributed for publication and display on www.USASpending.gov. Recipients are required to register with FSRS, collect the necessary data from subrecipients, and file subaward reports by the end of the month following the month in which the pass-through entity awards any subaward greater than $30,000.

FFATA specifies the data that should be captured for each pass-through entity and first-tier subrecipient of Federal awards, regardless of award type. To promote data consistency and reduce reporting burdens, existing agency data sources will be leveraged to pre-populate reports for pass-through entities as well as for subrecipients when available. Recipients are responsible for confirming the pre-populated data and providing any additional required information.

Included in these requirements is the need to report the names and total compensation of the five most highly compensated officers of the entity if the entity as part of their registration profile in SAM in the preceding fiscal year: 1) received 80 percent or more of its annual gross revenues in Federal grants, subawards, contracts, and subcontracts; and 2) received $25,000,000 or more in annual gross revenues from Federal grants, subawards, contracts, and subcontracts; and 3) had gross income, from all sources, of $300,000 or more; and 4) the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1). Additionally, recipient organizations may be required to verify the following information in FSRS:

- Organization UEI
- Name and Address of organization
- Parent UEI
- Assistance listing number
- FAIN
- Federal Awarding Agency of the grant

8.4.1.6 Invention Reporting

A complete list of the reporting requirements under the Bayh-Dole Act can be found at 37 CFR 401.14. The requirements also are specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.

In addition to complying with Bayh-Dole-related regulations, each NIH competing grant application and non-competing continuation progress report must indicate whether or not any subject inventions were made during the preceding budget period. If inventions were made, the recipient must also indicate whether they were reported.

The recipient also must submit an annual invention utilization report for all subject inventions to which title has been elected and inventions that have been licensed but not patented (research tools). The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

A recipient's failure to comply with invention reporting requirements and/or associated NIH policies on intellectual property and resource sharing may result in the loss of patent rights or a withholding of grant funds or other enforcement actions, including the imposition of specific terms and conditions.

Bayh-Dole regulations allow recipients to report inventions electronically (37 CFR 401.16). NIH requires electronic reporting through an Internet-based system, Interagency Edison. To meet the objectives of the Federal Financial Assistance Management Improvement Act of 1999 (P.L. 106-107), recipients are required to submit invention reports to NIH using iEdison. The system supports confidential transmission of required information and provides a utility for generating reports and reminders of pending reporting deadlines. Further information about the system, including instructions for creating an account needed to submit reports electronically, are on the iEdison site. Recipients also may contact the Division of Extramural Inventions and Technology Resources Branch, OPERA, OER. See Part III for contact information.

8.4.1.7 Financial Conflict of Interest Reports

Information related to FCOI reporting requirements can be found within Public Policy Requirements -- Financial Conflict of Interest.

8.4.1.8 NIH Disclosure Requirements

As part of the application preparation and submission process, and annual progress report submission, all individuals designated in an application as senior/key personnel are required to certify and submit information to assist reviewers and NIH staff in making informed recommendations and funding decisions. These disclosures are provided in the following proposal sections:

• Biographical Sketch; (see 2.3.7.12);

• Other Support (see 2.5.1); and

• Financial Conflicts of Interest (see 4.1.10)

Details on the required disclosures can be found in the NIH Disclosure Table. It is vital that submission of such disclosure information be taken seriously. Failure to comply with terms and conditions related to disclosure requirements may cause NIH to take action(s) to remedy non-compliance, such as disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action (see Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).. Further, violations that are potentially criminal will be referred to the NIH Office of Management Assessment for consultation with the HHS Office of Inspector General, the Department of Justice, or other law enforcement agencies, as appropriate.

8.4.2 Record Retention and Access

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH. See 2 CFR Part 200.334 for exceptions or qualifications to the 3-year retention requirement exist (e.g., if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period), the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken). Maintain the information for the retention period for other types of grant-related records, including F&A cost proposals and property records. See 2 CFR Part 200.334 and 2 CFR Part 200.337 for record retention and access requirements for contracts under grants.

These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

NIH, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the NIH award, to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents. The rights of access in this section are not limited to the required retention period but lasts as long as the records are retained. Pass-through entities must not impose any other access requirements upon non-Federal entities.

8.4.3 Audit

An audit is a systematic review or appraisal made to determine whether internal accounting and other control systems provide reasonable assurance of the following:

- Financial operations are properly conducted.
- Financial reports are timely, fair, and accurately.
- The entity has complied with applicable laws, regulations, and other grant terms.
- Resources are managed and used economically and efficiently.
- Desired results and objectives are being achieved effectively.

NIH recipients (other than Federal institutions) are subject to audit requirements in 2 CFR Part 200 Subpart F and in the NIHGPS (for types of organizations to which 2 CFR Part 200, Subpart F-Audit Requirements do not directly apply). In general, 2 CFR Part 200, Subpart F- Audit Requirements requires a State government, local government, or non-profit organization (including institutions of higher education) that expends $750,000 or more per year under Federal grants, cooperative agreements, and/or procurement contracts are required to have an annual audit by a public accountant or a Federal, State, or local governmental audit organization. The audit must meet the standards specified in generally accepted government auditing standards (GAGAS). The audit requirements for foreign recipients and for-profit recipients are addressed in the chapters of this NIHGPS that provide specific requirements for those types of recipients.

As specified in the NoA, all awards issued by NIH meet the definition of "Research and Development" at 2 CFR Part 200.1. As such, NIH grant awards are subject to the R&D cluster of program requirements in the compliance supplement. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Exhibit 10. Summary of Audit Requirements

Recipient Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Colleges & Universities (IHEs)	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Non-Profits	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
Hospitals	2 CFR 200.501	Federal Audit Clearinghouse (See contact information in Part III)
For-Profits	2 CFR 200.501	Audit Resolution Division (See contact information in Part III)
Foreign	NIH Grants Policy Statement (same as For-Profits)	Audit Resolution Division (same as For-Profits, see contact information in Part III)

When a recipient procures audit services, the procurement must comply with the procurement standards of 2 CFR Part 200, as applicable, including obtaining competition and making positive efforts to use small businesses, minority-owned firms, and women's business enterprises. Recipients should ensure that comprehensive solicitations made available to interested firms include all audit requirements and specify the criteria to be used for selection of the firm. Recipients' written agreements with auditors must specify the rights and responsibilities of each party.

2 CFR Part 200, Subpart F-Audit Requirements explains in detail the scope, frequency, and other aspects of the audit. Some highlights of this regulation are as follows:

- Covered organizations expending $750,000 or more per year in Federal awards are required to have an audit performed in accordance with the regulation. However, if the awards are under one program, the organization can have either a single organization-wide audit or a program-specific audit of the single program, subject to the provisions of 2 CFR Part 200.507. Prior to electing a program-specific audit, the recipient must obtain written prior approval from the NIH awarding IC. Covered organizations expending less than $750,000 in any year are exempt from these audit requirements in that year but must have their records available for review as required by Administrative Requirements—Monitoring—Record Retention and Access.
- The reporting package must contain the following:
    - Financial statements and schedule of expenditures of Federal awards.
    - Independent auditor's report, including an opinion on the financial statements and the schedule of expenditures of Federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
    - A schedule of findings and questioned costs.
    - If applicable, a summary of prior audit findings and a corrective action plan.
- An audit under 2 CFR Part 200, Subpart F-Audit Requirements is in lieu of a financial audit of individual Federal awards. However, Federal agencies may request additional audits necessary to carry out their responsibilities under Federal law or regulation. Any additional audits will build upon work performed by the independent auditor.
- The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the FAC at the address provided in Part III.

- A senior level representative of the auditee (e.g., state controller, director of finance, chief executive officer, or chief financial officer) must sign a statement to be included as part of the data collection that says that the auditee complied with the requirements of this part, the data were prepared in accordance with this part (and the instructions accompanying the form), the reporting package does not include protected personally identifiable information, the information included in its entirety is accurate and complete, and that the FAC is authorized to make the reporting package and the form publicly available on a web site. Exception: An auditee that is an Indian tribe or a tribal organization (as defined in the Indian Self- Determination, Education and Assistance Act (ISDEAA), 25 U.S.C. 450b(l)) may opt not to authorize the FAC to make the reporting package publicly available on a web site, by excluding the authorization for the FAC publication. If this option is exercised, the auditee becomes responsible for submitting the reporting package directly to any pass-through entities through which it has received a Federal award and to pass-through entities for which the summary schedule of prior audit findings reported the status of any findings related to Federal awards that the pass-through entity provided. Unless restricted by Federal statute or regulation, if the auditee opts not to authorize publication, it must make copies of the reporting package available for public inspection.

If the schedule of findings and questioned costs discloses an audit finding related to an HHS or NIH award or if the schedule of prior audit findings reports the status of any audit finding relating to an HHS or NIH award, the FAC will provide copies of the audit report to NEARC, OIG, HHS. NEARC will, in turn, distribute them within HHS for further action, as necessary. Audit reports should not be sent directly to the GMO. The threshold for reporting questioned costs is described in 2 CFR Part 200.516.

Recipients must follow a systematic method for ensuring timely and appropriate resolution of audit findings and recommendations, whether discovered as a result of a Federal audit or a recipient-initiated audit. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official (Action Official) concerning audit findings. Failure to submit timely responses may result in cost disallowance or other actions by NIH or HHS. At the completion of the audit resolution process, the recipient will be notified of the Action Official's final decision. The recipient may appeal this decision if the adverse determination is of a type covered by NIH or HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures). Refunds owed to the Federal government as a result of audit disallowances must be made in accordance with instructions issued by the Action Official or OFM.

It is imperative that recipients submit required 2 CFR Part 200, Subpart F audits within the time limits specified in the regulation. If recipients are delinquent in complying with the provisions of the regulation, NIH will take one or more actions that may result in the loss of Federal funds. No audit costs will be allowed either as F&A costs or direct costs to Federal awards if the required audits have not been completed or have not been conducted in accordance with the provisions of 2 CFR Part 200, Subpart F.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of audit costs.

8.5 SPECIFIC AWARD CONDITIONS AND REMEDIES FOR NONCOMPLIANCE (SPECIFIC AWARD CONDITIONS AND ENFORCEMENT ACTIONS)

A recipient's failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies. NIH generally will afford the recipient an opportunity to correct the deficiencies

before taking action unless public health or welfare concerns require immediate action. However, even if a recipient is taking corrective action, NIH may take proactive actions to protect the Federal government's interests, including placing specific conditions on awards or precluding the recipient from obtaining future awards for a specified period, or may take action designed to prevent future non-compliance, such as closer monitoring.

8.5.1 Specific Award Conditions: Modification of the Terms of Award

During grant performance, the GMO may include specific award conditions in the grant award to require correction of identified financial or administrative deficiencies as a means of protecting NIH's interests and effecting positive change in a recipient's performance or compliance. When specific conditions are imposed, the GMO will notify the recipient in writing of the nature of the conditions, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions. See 42 CFR Part 52.9 and 2 CFR Part 200.339.

The NIH awarding IC may withdraw approval of the PD/PI or other senior/key personnel specifically referenced in the NoA if there is a reasonable basis to conclude that the PD/PI and other such named senior/key personnel are no longer qualified or competent to perform the research objectives. In that case, the awarding IC may request that the recipient designate a new PD/PI or other named senior/key personnel.

Generally, the decision to modify the terms of an award (e.g., by imposing specific award conditions) is discretionary on the part of the NIH awarding IC and is not appealable.

8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If a recipient has failed to comply with the terms and conditions of award, NIH may take one or more enforcement actions which include disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action. NIH may also terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. The regulatory procedures that pertain to suspension and termination are specified in 2 CFR Parts 200.340 through 200.343.

a. NIH or the pass-through entity must provide the non-Federal entity a notice of termination
b. If the award is terminated for the non-Federal entity's material failure to comply with the Federal statutes, regulations, or terms and conditions of the Federal award, the notification must state that:
    1. The termination decision will be reported to the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS);
    2. The information will be available in the OMB-designated integrity and performance system for a period of five years from the date of the termination, then archived;
    3. Awarding agencies that consider making a Federal award to the non-Federal entity during that five year period must consider that information in judging whether the non-Federal entity is qualified to receive the Federal award, when the Federal share of the Federal award is expected to exceed the simplified acquisition threshold over the period of performance;
    4. The non-Federal entity may comment on any information the OMB-designated integrity and performance system contains about the non-Federal entity for future consideration by HHS awarding agencies. The non-Federal entity may submit comments to the recipient integrity and performance portal accessible through CPARS.
    5. Federal awarding agencies will consider the non-Federal entity comments when determining whether the non-Federal entity is qualified for a future Federal award.
c. Upon termination of an award, NIH must provide the information required under FFATA to the Federal web site established to fulfill the requirements of FFATA and update or notify any other relevant government-wide systems or entities of any indications of poor performance as required by 41 U.S.C. 417b and 31 U.S.C. 3321. See also the requirements for Suspension and Debarment at 2 CFR Part 180.

NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the grant if the recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate a grant when necessary, such as to protect the public health and welfare from the effects of a serious deficiency. Termination may be appealed under NIH and HHS grant appeals procedures (see Administrative Requirements—Grant Appeals Procedures).

A grant also may be terminated, partially or totally, by the recipient or by NIH with the consent of the recipient. If the recipient decides to terminate a portion of a grant, NIH may determine that the remaining portion of the grant will not accomplish the purposes for which the grant was originally awarded. In any such case, NIH will advise the recipient of the possibility of termination of the entire grant and allow the recipient to withdraw its termination request. If the recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire grant.

See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost for the allowability of termination costs. Allowability of these costs does not vary whether a grant is terminated by NIH, terminated at the request of the recipient, or terminated by mutual agreement.

Withholding of support is a decision not to make a non-competing continuation award within the current competitive segment. Support may be withheld for one or more of the following reasons:

- Adequate Federal funds are not available to support the project.
- A recipient failed to show satisfactory progress in achieving the objectives of the project.
- A recipient failed to meet the terms and conditions of a previous award.

- For whatever reason, continued funding would not be in the best interests of the Federal government.

The recipient may appeal NIH's determination to deny (withhold) a non-competing continuation award because the recipient failed to comply with the terms and conditions of a previous award.

8.5.3 Other Enforcement Actions

Depending on the nature of the deficiency, NIH may use other means of promoting recipient compliance. Other options available to NIH include, but are not limited to conversion from an advance payment method to a reimbursement method or disallow (deny) all or part of the cost of the activity or action not in compliance. Other actions may include suspension or debarment of an organization or individual under Government-wide Debarment and Suspension rules provided at 45 CFR Part 76, and other available legal remedies, such as civil action. Suspension under 45 CFR Part 76, implementing E.O.s 12549 and 12689, "Debarment and Suspension," is a separate action from the "suspension" of an award as a post-award remedy, as described in Suspension, Termination, and Withholding of Support above. The subject of debarment and suspension as an eligibility criterion is addressed in Completing the Pre-Award Process—Determining Eligibility of Individuals and Public Policy Requirements and Objectives—Debarment and Suspension.

8.5.4 Recovery of Funds

NIH may identify and administratively recover funds paid to a recipient at any time during the life cycle of a grant. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost sharing, funds in the recipient's account that exceed the final amount determined to be allowable, or other circumstances. NIH guidance on the repayment of grant funds that are unrelated to audit findings can be found on the OER Web site.

8.5.5 Debt Collection

The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L.104-134, 110 Stat. 1321, April 26, 1996); and, the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for HHS in 45 CFR 30. NIH is required to collect debts due to the Federal government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by recipients.

When NIH determines the existence of a debt under a grant, written debt notification will be provided to the recipient. Unless otherwise specified in law, regulation, or the terms and conditions of the award, debts are considered delinquent if they are not paid within 30 days from the date the debt notification is mailed to the recipient. Delinquent debts are subject to the assessment of interest, administrative cost charges, and penalties. The interest on delinquent debts accrues on the amount due beginning on the date the debt notification is mailed to the recipient.

If a recipient appeals an adverse monetary determination under 42 CFR Part 50, Subpart D, or 45 CFR Part 16, interest will accrue but assessment will be deferred pending a final decision on the appeal. If the appeal is not successful, interest will be charged beginning with the date the debt notification was mailed to the recipient, not the date of the appeal decision. Interest charges will be computed using the prevailing rate in effect on the date the debt notification is mailed, as specified by the Department of the Treasury and 45 CFR Part 30.13(a)(2).

8.6 CLOSEOUT

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records. If a recipient does not submit all required closeout reports within a year of the period of performance end date, NIH must report the recipient's failure to comply with the terms and conditions of award in FAPIIS and initiate unilateral closeout.

Failure to submit timely and accurate closeout documents may affect future funding to the organization. Failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding or further awards, suspension or termination. NIH will close out a grant as soon as possible after the end date of the period of performance (no later than one year after the period of performance end date in accordance with 2 CFR Part 200.344) if the grant will not be extended or after termination.

Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due the recipient or NIH. Closeout of a grant does not automatically cancel any requirements for property accountability, (8.3.3.2.1 Exempt Property and 8.3.3.2.2 Nonexempt Property), record retention, or financial accountability. Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of the grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual FFR is submitted. (See 8.4.2 Record Retention and Access, for further information). Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the Federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Recipients must submit a final FFR, Final RPPR, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends.

A subrecipient must submit to the recipient, no later than 90 calendar days (or an earlier date as agreed upon by the recipient and subrecipient) after the end date of the period of performance, all reports as required by the terms and conditions of award.

8.6.1 Final Federal Financial Report

A final FFR is required for

- any award that is terminated,
- any award that is transferred to a new recipient, or
- any award, including awards under SNAP, which will not be extended through award of a new competitive segment.

Recipients are required to electronically submit the final FFR through the Payment Management System. The final FFR must cover the entire competitive segment or as much of the competitive segment as has been funded before termination. Final FFRs must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Federal share of expenditures reported on the final FFR and the net cash disbursements reported in PMS on the Transactions section of the FFR. . It is the recipient's responsibility to reconcile reports **prior** to submission to PMS and to the NIH awarding IC. Withdrawal of the unobligated balance following completion date or termination of a grant is not considered an adverse action and is not subject to appeal (see Administrative Requirements—Enforcement Actions—Recovery of Funds).

When the submission of a revised final FFR results in additional claims by the recipient, NIH will consider the approval of such claims subject to the following minimum criteria:

- The recipient must indicate why the revision is necessary and explain and implement internal controls that will preclude similar occurrences in the future.
- The charge must represent otherwise allowable costs under the provisions of the grant.
- There must be an unobligated balance for the budget period sufficient to cover the claim.
- The funds must still be available for use.
- NIH must receive the revised final FFR within one year of its original due date.

8.6.2 Final Research Performance Progress Report

A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR.

A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the NIH RPPR web site and any specific requirements set forth in the terms and conditions of the award. In addition to the standard requirements detailed in those Instructions, recipients should also report additional information required by the awarding IC in program-specific final progress report instructions.

Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the RPPR Instructions.

8.6.3 Final Invention Statement and Certification

The recipient must submit a Final Invention Statement and Certification (HHS 568), whether or not the funded project results in any subject inventions, and whether or not inventions were previously reported. The HHS 568 must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, and it must be signed by an AOR. The completed form should cover the period from the original effective date of support through the completion date or termination of the award, and it should be submitted to the NIH awarding IC. If there were no inventions, the form must indicate "None." For certain programs (activity codes = C06, , D42, D43, D71, DP7, G07, G08, G11, G13, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UH4, UC6, UC7, UG4, UR2, X01, X02, Ts, and Fs), the Final Invention Statement and Certification is not currently required. For questions, the recipient should contact NIH awarding IC for specific instructions.

When invention reporting is required, the HHS 568 does not relieve the responsible party of the obligation to assure that all inventions are promptly and fully reported directly to NIH, as required by terms of the award. Copies of the HHS 568 form are available on the iEdison web site at http://iEdison.gov and at http://grants.nih.gov/grants/forms.htm.

8.6.4 Submission of Closeout Documents

All closeout documents must be submitted electronically via eRA Commons (Final RPPR and Final Invention Statement) or PMS (Final FFR), as applicable. NIH no longer accepts paper or e-mail

submissions.

8.7 GRANT APPEALS PROCEDURES

HHS permits recipients to appeal certain post-award adverse administrative decisions made by HHS officials (see 45 CFR Part 16 and appendix to Part 16). NIH has established a first-level grant appeal procedure that must be exhausted before an appeal may be filed by the recipient with the Departmental Appeals Board (DAB) (see 42 CFR Part 50, Subpart D). NIH will assume jurisdiction for the following adverse determinations set forth in 42 CFR Part 50.404:

- Termination, in whole or in part, of a grant for failure of the recipient to carry out its approved project in accordance with the applicable law and the terms and conditions of award or for failure of the recipient otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
- Determination that an expenditure is not allowable under the grant has been charged to the grant or that the recipient has otherwise failed to discharge its obligation to account for grant funds.
- Denial (withholding) of a non-competing continuation award for failure to comply with the terms of a previous award.
- Determination that a grant is void (i.e., a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

The formal notification of an adverse determination will contain a statement of the recipient's appeal rights. In the first level appeal of an adverse determination, the recipient must submit a request for review to the NIH official specified in the notification, detailing the nature of the disagreement with the adverse determination and providing supporting documents in accordance with the procedures contained in the notification.

"The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of the recipient's position with respect to such issue(s) and the pertinent facts and reasons in support of the recipient's position. In addition to the required written statement, the recipient shall provide copies of any documents supporting its claim." 42 CFR Part 50.406(b).

The recipient's request to NIH for review must be submitted no later than 30 days after the written notification of the adverse determination is received; however, an extension may be granted if the recipient can show good cause why an extension is warranted (42 CFR Part 50.406(a)).

If the NIH decision on the appeal is adverse to the recipient or if a recipient's request for review is rejected on jurisdictional grounds, the recipient then has the option of submitting a request to the DAB for a further review of the case in accordance with the provisions of 45 CFR Part 16. A prospective appellant must submit a notice of appeal to the DAB within 30 days after receiving the final NIH decision. "The appellant must have exhausted any preliminary appeal process required by regulation." 45 CFR Part 16.3 (c).

In addition to the adverse determinations indicated above, the DAB is the single level of appeal for disputes related to the establishment of F&A cost rates, research patient care rates, and certain other cost allocations used in determining amounts to be reimbursed under NIH grants (e.g., cost allocation plans negotiated with State or local governments and computer, fringe benefit, and other special rates. The determination leading to such disputes may be made by an HHS official other than the GMO and may affect NIH grants as well as other HHS grants.

EXHIBIT 12

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al. Plaintiffs, v. ROBERT F. KENNEDY, JR., et al., Defendants.	Civil Action No. _____

DECLARATION OF DENISE BARTON

I, Denise Barton, declare as follows:

1. I am a resident of the Commonwealth of Massachusetts. I am over the age of 18. I have been an attorney since 1994 and am licensed to practice in the Commonwealth of Massachusetts. If called as a witness, I could and would testify competently to the matters set forth below.
2. I am currently employed by the University of Massachusetts, in its Office of the General Counsel, as its Chief Deputy General Counsel.
3. As Chief Deputy General Counsel for the University of Massachusetts, I have personal knowledge of the matters set forth below or have knowledge of the matters based on my review of information and records provided to me by University of Massachusetts employees and believe that information to be true.
4. The University of Massachusetts includes its five campuses (the University of Massachusetts Amherst, the University of Massachusetts Boston, the University of Massachusetts Chan Medical School, the University of Massachusetts Dartmouth, and the University of Massachusetts Lowell), as well as the University of Massachusetts Office of the President.

See M.G.L. c. 75. The University of Massachusetts maintains business records in the ordinary course of University of Massachusetts business which include, *inter alia*, records concerning grant proposals submitted to and funding received from the National Institutes of Health ("NIH") by the University of Massachusetts.

5. I am also providing this declaration to explain the irreparable harmful impacts of NIH's abrupt and ill-supported cancellation of certain grants to the University of Massachusetts.

6. I am also providing this declaration to explain the impacts of NIH's delay in evaluating applications for future grants, delay in funding projects that have passed peer review, and denial of grant applications without consideration of scientific merit.

7. The NIH funding blockade and outright grant cancellations severely impact the University of Massachusetts in its entirety: all five campuses have and will suffer short-term and long-term detriment. I have provided the following information to explain some of the impact on two of the University of Massachusetts' campuses and the people whose research they serve: the University of Massachusetts Amherst ("UMass Amherst") and the University of Massachusetts Chan Medical School ("UMass Chan Medical School"), reserving rights to supplement this declaration with further information concerning the impact on those campuses as well as the impacts on the remainder of the University of Massachusetts.

8. In federal fiscal year 2024, University of Massachusetts campuses received NIH funding to support over 501 projects, totaling $248 million dollars.

9. UMass Chan Medical School is the Commonwealth of Massachusetts' only public medical school. As such, UMass Chan Medical School serves a unique role in the education of physicians, nurses, and scientists as well as in the performance of research that serves the public good. In keeping with the University of Massachusetts' public mission, UMass Chan

Medical School focuses its research efforts on addressing unmet medical needs in ways that benefit all people in the Commonwealth and beyond. To carry out its public medical research mission, UMass Chan Medical School relies on NIH funding.

10. In fiscal year 2024, UMass Chan Medical School received 365 awards for approximately $197,039,162 in funding from NIH.

11. UMass Amherst is the flagship institution of the Commonwealth of Massachusetts and is a nationally ranked public land-grant research university that seeks to expand educational access, fuel innovation and creativity, and share and use its knowledge for the common good. UMass Amherst offers a full range of undergraduate, graduate and professional degrees, enrolling approximately 22,800 undergraduate students and nearly 7,500 master's and Ph.D. students across more than 200 degree programs and 60 departments. Students are supported by nearly 1,800 faculty and 4,500 staff who play critical roles supporting teaching, research, discovery, and learning. In the 2022 fiscal year, UMass Amherst generated $2.9 billion for the Massachusetts economy and supported more than 13,200 external jobs.

12. The work done by UMass Amherst on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs. UMass Amherst, along with other UMass campuses, is the largest provider of Science, Technology, Engineering and Mathematics ("STEM") workforce to the Massachusetts economy.

13. In fiscal year 2024, UMass Amherst received 130 awards for approximately $42 million dollars in funding from NIH.

UNLAWFUL TERMINATIONS

14. As of March 27, 2025, the University of Massachusetts has had four active NIH grants unilaterally terminated:

    a. "Effect of Medicaid accountable care organizations on behavioral health care quality and outcomes for children," award number 3R01MH134176-02S1, with an award of $99,974, was terminated on March 21, 2025. Ex. B.

    b. "Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults," award number 5R33HD107988-04, with an award of $278,952, was terminated on March 21, 2025. Ex. D.

    c. "Adapting mHealth interventions to improve self-management of HIV and substance use among emerging adults in Zambia," award number 5R34MH124081-02, with an award of $671,459, was terminated on March 21, 2025. Ex. F.

    d. "Applying deep learning for predicting retention in PrEP care and effective PrEP use among key populations at risk for HIV in Thailand," award number 5R03MH130275-02, with an award of $76,214, was terminated on March 21, 2025. Ex. H.

15. The research project leaders ("Principal Investigators," or "PIs") were notified of these terminations via a termination letter sent by NIH's Office of Extramural Research. Each letter stated that the termination was "pursuant to the 2024 National Institutes of Health

('NIH') Grants Policy Statement, and 2 C.F.R. § 200.340(a)(2)," for failure to "effectuate[] agency priorities." Exs. B, D, F, H.

16. The four termination letters received by the University of Massachusetts purported to justify the terminations with the following ostensibly boilerplate language:

    a. NIH Grant Number 5R34MH124081-03: "It is the policy of NIH not to prioritize research activities based on diversity, equity, and inclusion ("DEI") no longer effectuates agency priorities. Therefore, this project is terminated."

    b. NIH Grant Number 3R01MH134176-02S1: "This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs."

    c. NIH Grant Number 5R33HD107988-04: "This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs."

    d. NIH Grant Number 5R03MH130275-02: "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous

equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."

17. Each termination letter also includes the following language, immediately subsequent to the language quoted in ¶ 16, *supra*: "Although 'NIH generally will suspend (rather than immediately terminate) a grant and allow the decision,' no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

18. Additionally, 2 awards in which the University of Massachusetts was a subawardee have been terminated.

    a. "Faithful response II: COVID-19 rapid test-to-treat with African American churches," award number U01MD018310, with an award of approximately $126,000, was terminated on March 21, 2025. This was a pass-through award via the University of Missouri at Kansas City to UMass Amherst.

    b. "Training the long-term services and supports dementia care workforce in provision of care to sexual and gender minority residents," award number 3R01AG075734-02S1, with an award of approximately $65,000, was

terminated on March 21, 2025. This was a pass-through award via the University of Minnesota to the University of Massachusetts Boston.

19. No PI for any of these projects was subjected to any inquiries from the NIH program officer or other officials. No warning was provided that projects were at-risk to lose funding.

20. Terminations are actively being conducted by NIH, with new programs and projects being cut weekly if not daily. For example, on April 2, 2025, a UMass Amherst PI was informed the Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC) program—aimed at funding career development and research projects for scientists from underrepresented backgrounds—has been terminated, effectively ending future funding for grants administered under its auspices.

21. These terminations have set in motion far-ranging and potentially irreversible harms. One of the terminated grants supplemented a project examining the impacts of Accountable Care Organizations in the state Medicaid program on quality of care and healthcare utilization for children with mental health disorders; in particular, this grant provided resources to include LGBTQIA+-identifying youth into the study to ensure their experiences were documented and informed the project's results. As a result of the termination of this grant, those voices will not contribute to the study.

22. Additionally, this grant was led by a junior faculty member whose tenure track status relies in large part on this project. This abrupt cancelation places this young scientist's future at UMass Amherst and his career in jeopardy. Additionally, the grant contributed to the salaries for two full-time staff members; both are talented researchers now contemplating leaving UMass Amherst to find more secure employment. One has a long-standing working relationship with the PI, and their departure would negatively impact the PI's other,

uncanceled research projects. Both employees have institutional knowledge and training that cannot be easily, cheaply, or quickly replaced, and multiple projects may have their research goals compromised as a result.

DELAYS IN THE APPLICATION REVIEW PROCESS

23. A PI pursuing a grant for their research will submit an application to a member institute of NIH, known as "ICs," with a project proposal that includes, *inter alia*, a description of the project, the budget of the project, the funds sought, and the project start date.

24. The IC will review the application through 2 rounds of organized review: peer-review for scientific merit ("study section review") and advisory council review.

    a. In study section review, a group of non-federal scientists with a focus relevant to the proposed project will review the scientific merits of the project, then assign a project score (ranging from 10-90, with 10 being best); this score is then converted into a percentile, indicating how the scientific merit of that project is ranked against its peer applicants to the same IC for the same cycle. Typically, ICs will publicly release an annual "payline" number (ranging from 8%-20%), which indicates the cutoff point.[1] Projects scored such that their percentile ranking is superior to the payline number are considered to have "fundable scores," a term used by institutions of higher education ("IHE") and NIH.

[1] Some ICs do not publish a payline. Additionally, some study sections (often those focusing on projects with special emphases) only issue a score, not a percentile. Regardless, the University of Massachusetts has sufficient historical data from its own experiences and that of peer IHEs to predict what scores constitute "fundable" for each IC.

b. In advisory council review, the council confers with the program officer (the employee at NIH tasked with interfacing with PIs and overseeing NIH's relationship with awarded projects) to determine whether to recommend a project to the IC administrator for funding. It is exceedingly rare for a project with a fundable score not to be recommended, and almost unheard of for a project so recommended not to be funded. Grants that fall significantly below the pay line are typically not discussed by advisory councils.

c. Between the study section and the advisory council meeting, investigators that have scores (typically) better than 40 are sent a request for "Just in Time" information ("JIT"). As part of the JIT request, investigators are asked to provide the most updated information about their other sources of support for their research, confirm that they have approval by the appropriate ethics boards (for work involving animals or human subjects), and certify human subjects training for key personnel, if needed.

25. Once a project is given a fundable score, typically the IHE will undertake preparations necessary to ensure timely commencement of a new project and efficient use of NIH funds. These may include, *e.g.*, acquiring cell cultures, breeding animals (many of which must be aged to certain requirements), and hiring staff. Although these decisions often occur prior to receipt of a Notice of Award, these preparations are necessary for scientific integrity and to maximize efficient use of NIH funds. For extant projects seeking competitive renewal of funding, prior to the initiation of the new award period, the PI must make determinations regarding extending contracts for researchers, maintaining cell cultures, and continued

expenses related to test subjects. If the score is fundable, the project is expected to continue and to be supported by a renewal of the funding so that the work is not interrupted.

26. NIH has historically implemented a three-cycle schedule for accepting and evaluating grant applications.[2] For example, in Cycle II, applications have deadlines ranging from May 25 – September 7; study section review is in October and November; advisory council review is in January; and projects may schedule start dates for April 1. In Cycle III, applications have deadlines ranging from September 25 – January 7; study section review is in February and March; advisory council review is in May; and projects may schedule start dates for July 1.

UNEXPLAINED AND UNREASONABLE DELAY OF REVIEW OF PENDING GRANT APPLICATIONS.

27. As of April 3, 2025, UMass Chan Medical School has approximately 252 projects awaiting review that, per NIH's published schedule, is overdue.[3]

    a. 205 proposals totaling $538,785,366 ($112,828,561 in their first year) are awaiting NIH study section review.

    b. 29 proposals totaling $34,000,074 ($7,727,829 in the first year) that received fundable scores, awaiting NIH advisory councils that have been rescheduled and delayed and are, therefore, still awaiting Notice of Award.

[2] NIH lists its schedule of review for each of three annual cycles of grants. *Review and Award Cycles*, *available at* https://grants.nih.gov/grants-process/submit/submission-policies/standard-due-dates.

[3] The data pertaining to the status of each of UMass Chan Medical School's and UMass Amherst's pending grant applications, *see* ¶ 28, *infra*, are drawn from eRA Commons (the NIH reporting system), and reflect the University of Massachusetts' best estimates as of April 3, 2025.

c. 18 proposals totaling $66,119,813 ($14,012,114 in the first year) that received fundable scores, were reviewed by NIH advisory council, and are awaiting a Notice of Award. These projects all had council review completed as of February 28, 2025, and anticipated start dates of April 1, 2025, or sooner.

28. As of April 3, 2025, UMass Amherst has approximately 92 projects awaiting review that, per NIH's published schedule, is overdue.

a. 67 proposals totaling $137,198,101 ($30,343,184 in the first year) awaiting NIH study section review.

b. 11 proposals totaling $33,114,431 ($6,873,456 in the first year) that received fundable scores, awaiting NIH advisory council and Notice of Award. These include 3 new proposals and one competitive renewal with start dates of April 1, 2025.

c. 14 proposals totaling $39,115,113 ($8,636,336 in the first year) that received possibly fundable scores, awaiting NIH advisory council and possible Notice of Award.

29. Prior to January 20, 2025, the typical timeline for an NIH grant from submission through review, approval and project start date was about eleven months. The typical timeline of the evaluation process for grant applications at NIH looked like this:

a. Submission at month 0.

b. Assignment to a study section at months 1-3.

c. Review at study section at months 4-5.

d. Recommendation made at Council at months 7-8.

e. Notice of award at months 9-11.

f. Award set-up at months 10-12.

30. Since January 20, 2025, the cadence of study section and/or council meetings has been significantly altered by the NIH. The NIH publishes a "NOTICE of Closed Meetings" in the Federal Register to schedule Study Sections or Council Meetings. NIH listed 63 study sections as scheduled between January 21, 2025, and March 8, 2025, through the Center for Scientific Review at NIH, 167 fewer than the same period in 2024. (This does not include reviews done by various institutes at NIH.) Indeed, UMass Amherst is aware of 6 study sections previously scheduled for this period and these do not appear on the NIH list.

31. NIH lists 387 study sections between March 9, 2025, and June 20, 2025, through the Center for Scientific Review at NIH, 69 more than the same period in 2024, suggesting that some, and possibly all, of the canceled study sections have been rescheduled. Each IC typically holds a meeting of its advisory council three times per year, at which time all applications that passed through study section review are considered. These meetings are typically held 1-2 months before the earliest permissible start date for projects in that cycle.

32. Cycle II advisory council meetings are typically scheduled for January. In 2025, 14 of the 15 Cycle II advisory council meetings—every meeting scheduled for after January 20, 2025—was canceled, only recently rescheduled for April and May. As of April 1, 2025, 16 Cycle II applications with fundable scores still have not received a date for an advisory council meeting (5 from UMass Chan Medical School, 11 from UMass Amherst). Of these, 4 had start dates of April 1, 2025.

33. Cycle III advisory council meetings are typically scheduled for May; to date, not a single Cycle III advisory council meeting has been noticed in the Federal Register. Due to the

backlog of Cycle III study sections, it is unclear whether those applications will have even completed their first round of review prior to May, and, as May will feature multiple advisory council meetings to review the backlog of Cycle II applications, it is unclear when those meetings will be able to occur. Many Cycle III projects have start dates of July 1.

34. Due to the unpredictable and unplotted review schedule encumbering Cycle II and III applications, it is impossible to predict or plan around delays facing the Cycle I applications presently being submitted to NIH.

35. Since January 20, 2025, due to the continued cancellation, rescheduling, and re-cancellation of NIH study section and advisory council meetings, it is anticipated that the timeline for full review of grant applications could extend to 15-16 months at best.

36. Should advisory council meetings occur at the earliest possible opportunities and study section reviews face no further delays, the best-case scenario for evaluation schedule in 2025 would be:

    a. Submission at month 0.

    b. Assignment to a study section at months 1–3.

    c. Review at study section at months 4–-5 (assuming that study section is being held at the normal scheduled cadence).

    d. Recommendation made at Council at months 11–13 (4–5-month delay) (approximately 1 month after the earliest permissible project start date).

    e. Notice of award at months 13–15 (4–5-month delay, which is at least 3 months *after* the expiration of the current award in the case of competitive renewal application).

f. Award set-up at months 14–16 (4–5-month delay) (approximately 4 months after the earliest permissible project start date).

37. Given the magnitude of the University of Massachusetts' grant activity in each cycle, four plus months of delay of expected funding has already created disruption in the operations of laboratories funded by those grants. For example, at UMass Chan Medical School, the disruption of the anticipated flow of funds precipitated by the abrupt and unannounced change of usual practice has led to the planned furlough of hundreds of personnel and the cancellation of nearly all acceptances of new graduate students for the fall 2025 admissions cycle.

38. There are some differences, described below, between a new grant application and "competitive grant renewal" in that there is a practical difference for PI and lab personnel if the renewal is not awarded.

a. New applications are generally activities that have not yet been initiated and are extensions/new directions based on preliminary findings, data, and hypotheses that the lab has generated and plans to pursue with the new award funds. Once an NOA is received, the work will commence. In a typical timeline, after receiving a fundable score, a PI will start to plan for initiation of the projects in the approximately 4 months between Study Section, Council approval and issuance of the NOA.

b. Competitive renewals are the next multi-year phase of work that has been previously funded. The activities planned are generally extensions of currently ongoing projects. Labs will usually have highly trained staff, students, postdocs, equipment, live cells, and animal models in place and

working that, without continued funding, will be terminated and/or shut down.

c. For example, one investigator who has a fundable score on a competing renewal application reached the end of their current NIH funding on March 31, 2025. The relevant Council meeting, which was initially canceled indefinitely, has been rescheduled for May 22, 2025. If the grant is recommended and subsequently approved in May, this will result in a funding gap of at least two to three months. During this time, the PI, the academic department, and the college and central administration will divert funds from other budgets to continue salary payments to existing personnel and a limited amount of funding for critical supplies. The research will certainly be disrupted by the funding interruption.

39. UMass Amherst currently has submitted 67 grant applications, totaling $137,198,101, as part of the upcoming Cycle I, all awaiting study section review. UMass Chan Medical School currently has submitted 171 grant applications, totaling $503,520,399 as part of that same cycle, all awaiting study section review. Because of the delays in study sections, the recent reductions in force at NIH, and the backlog of review sessions, it is highly likely that Cycle I applications will be materially delayed in being evaluated, to the detriment of the University of Massachusetts.

40. While the study section review for most projects is conducted through the NIH's centralized body, the Center for Scientific Review ("CSR"), many of the more complex and specialized projects were typically reviewed through study sections within the relevant IC, as well as applications solicited via that IC's requests for applications ("RFA"). NIH has recently

announced a "centralization" of study section review, meaning for non-CSR projects a potential limit to each IC's ability to direct/solicit specific research content areas, centralizing control of what gets funded. This runs counter to the Duties and Authority of the NIH Director, 42 U.S.C. § 282(b)(9) ("[NIH Director] shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title and that, after such review, the research is reviewed in accordance with section 289a–1(a)(2) of this title by the appropriate advisory council under section 284a of this title before the research proposals are approved for funding," as well as the purpose of the councils, 42 U.S.C. § 284a.

41. There are numerous examples throughout the University of Massachusetts of the grants that have fallen behind, and the impacts of that delay, because of the NIH's arbitrary rolling blockade on the grant approval process. What follows are several examples of the UMass Chan Medical School grants that NIH is blocking by its abrupt cancellation and delay of advisory council meetings. These exemplar grants all concern significant unmet medical needs, including pediatric cancer, Alzheimer's Disease, and the biological basis of substance use disorder. NIH's administrative blockade is harmful to the advancement of research in these areas, to the training and development of the future generation of researchers, and to the people this research would help.

42. One example of research projects kneecapped by the funding delay are a series of projects administered by a UMass Chan Medical School PI, who, is conducting three research projects with NIH funding that will terminate over the next twelve months, focused on pediatric neuro-oncology and traumatic brain injury. The PI also has two applications for other projects under consideration that have been affected by NIH's evaluation delay—

Project A has received a fundable score that is well within the applicable payline, and Project B has received a favorable score that is potentially fundable, falling just within the funding range.

a. Project A had advisory council review scheduled for late January; that meeting was canceled, then in early March NIH updated the status of that grant to "Council review completed," the program officer confirmed that both levels of review had been conducted, and then, confusingly, an advisory council review was scheduled for April 22, 2025.

b. Project B had advisory council review scheduled for early February; that meeting was canceled. The program officer has not responded to multiple inquiries via email. The advisory council meeting has been rescheduled for May 22, 2025.

43. Because of the delays to decisions on these two fundable projects, the active research being engaged in this PI's lab has suffered. One researcher has been furloughed to 50%, with the expectation that he will be terminated in June. Several lines of investigation have been closed, including drug screening and therapeutic development work for the pediatric neuro-oncology projects. The PI has been forced to decline to hire a student that would have otherwise supported one of those projects because of the lack of funding. And nearly all new experimental work has been terminated, so as to preserve as much funding as possible to support salary of the members of the research team.

44. Due to the loss of personnel necessitated by delays to pending applications, active research is harmed: investigations into treatment for a form of pediatric brain tumor, and development of

a commercially viable mechanism for delivery of gene therapy for pediatric neuro-oncology, new treatments for traumatic brain injury have been terminated.

45. Another example of a UMass Chan Medical School grant that has been hobbled by the NIH rolling blockade is a grant concerning one of the major obstacles to developing effective treatments for degenerative diseases of the brain: a paucity of genetic targets against which to direct therapeutic efforts. Recent human studies have revealed a robust and reproducible link between polymorphisms (gene variants) in the MS4A family of genes and Alzheimer's Disease ("AD") or related neurodegenerative disorders. In this grant, the PI, a UMass Chan Medical School Associate Professor, Program in Molecular Medicine will characterize the role of MS4A genes in degenerative brain diseases and anticipates that insights gained will inform the development of new treatments for these devastating disorders.

46. The NIH Grant number is R01AG089801, and it is entitled "Elucidation of the mechanisms by which Ms4a genes regulate neurodegeneration in Alzheimer's Disease and related disorders."

47. The application submission date was July 9, 2024. The anticipated start date was April 1, 2025. JIT information was submitted on March 21, 2025, and advisory council review was set for January 28, 2025. That review session was canceled, then rescheduled for April 22, 2025. In a typical year, the expected award notice date was March-April 2025. This grant has a score of 28 (placing it in the 13th percentile). With NIH's National Institute of Aging's payline at 17th percentile, UMass Chan Medical School anticipated that this grant would pass Council review and be awarded.

48. In preparation for the start date of this grant, UMass Chan Medical School hired two postdoctoral fellows in anticipation of the funding using a combination of institutional funds

and existing foundation grants to be prepared for the start of the grant, which is the ordinary manner in which scientific research of this nature proceeds. In addition, the experiments associated with this grant involve a significant number of different genetically modified mouse cell lines and neurodegenerative mouse models that need to be bred and aged out so that neurodegenerative phenotypes appear. UMass Chan Medical School began this process in anticipation of this grant being awarded, paying for the animal costs associated with this research using other funding sources to be ready to go as soon as grant funding is received.

49. UMass Chan Medical School must take immediate action to ensure a timely start date. If NIH does not make a decision soon, the PI will have to terminate the mouse experiments that he had begun as well as lay off the people that were hired in anticipation of this work being funded. The PI has used existing funds to the extent possible to get this project started. However, if this grant is not funded, as those additional resources are finite and limited, the PI fears that it will not be possible to continue this line of investigation without some outside intervention, such as another funding source.

50. This work is critical. Alzheimer's disease ("AD") is a debilitating neurodegenerative disorder that affects more than 6 million Americans, and its incidence is only increasing as our population ages. Current therapeutic interventions for this disease are highly limited in both number and efficacy indicating that new approaches are needed. UMass Chan Medical School's work has led to the identification of a series of compounds that will form the basis of new therapies for diseases that devastate millions of Americans, their families, and cost the country untold billions of dollars annually. This work will provide significant insight into the role that Ms4a genes play across neurodegenerative diseases like AD and take a significant step closer to developing therapies targeting these genes. UMass Chan Medical

School's research represents exactly the kind of success story that funding of biomedical sciences strives for. The uncertainty caused by the NIH blockade has created significant stress and anxiety in those working on this important research, may lead to personnel terminations, and may require slowing down or cessation of work that has the potential to have a significant impact on human health for this country.

51. A third example of a UMass Chan Medical School grant that has been hobbled by the NIH blockade is a grant concerning adeno-associated viruses ("AAV") which have been used to successfully deliver life-saving gene therapies in children. The UMass Chan Medical School PI for this grant (number RO1GM155648), entitled "Interrogating the roles of truncated/mutated inverted terminal repeat sequences in adeno-associated virus vectors in transgene stability through episome formation and host cell genome integration" is an Assistant Professor in the Gene Therapy Center. This work seeks to further improve the safety and performance of the viral vectors and will specifically define whether mutations in inverted terminal repeat ("ITR") sequences, which are the last remnants of viral elements found in AAV-based gene therapy vectors, can influence the stability and safety of genes being delivered. Using advanced next-generation sequencing approaches and appropriate cell culture and animal models, this work will help to link a previously enigmatic feature of AAV genomes to imperfections observed in vector genomes that result from potentially avoidable manufacturing errors. The project will help to inform whether heterogeneity in ITRs are risk factors for host-cell integration and tumorigenesis.

52. The application date for this grant was July 05, 2024. Its anticipated start date was April 01, 2025. The JIT was submitted on December 05, 2024, and the Council date was scheduled for February 06, 2025. That date was canceled, then rescheduled for May 22, 2025. The

expected award notice date in a typical year was March-April, 2025. This grant has an Impact Score of 22 (placing it in the 5th percentile), which is a fundable score.

53. To ensure timely completion of the project aims, UMass Chan Medical School will need to hire a PhD-level (Postdoctoral Associate) Bioinformatician that has experience in analyzing next-generation sequencing data and a Research Technician, preferably with training in molecular biology, handling of laboratory mice, and cell culture-based assays. Both hires will need sufficient time to be trained on techniques needed to execute project goals. The project will also require the use of humanized mouse models, which will be new to the research group. Laboratory personnel will need to be trained on how to handle and care for these mice. Since these mice are costly (approximately $3,500 per animal), proper training is absolutely necessary to limit experimental error and waste.

54. Decisions concerning this grant need to be made immediately and UMass Chan Medical School needs to decide whether to cancel the project or risk its own resources. Delays in NIH funding, coupled with NIH's actions concerning indirect costs, have led to furloughs and layoffs of postdocs and research associates. At the risk of losing more essential personnel and support staff, the need for action is immediate.

55. Gene therapy has revolutionized how genetic diseases are being treated yet many unknowns still limit their wider use. This work will provide vital insights into the safety of AAV-based gene therapy vectors, specifically, whether mutations in ITR elements can drive vector integration into the host genome – a risk factor for tumorigenesis. More than 4,000 patients have received the Zolgensma gene therapy for spinal muscular atrophy since its approval by the FDA. The technologies and expertise developed by the PI at UMass Chan Medical School are unique to the field. They are the only research team in the world that can

immediately address whether mutations within ITR elements of AAV vectors are risk factors for cancer. The high impact score received on this grant and favorable critiques by all three reviewers reflects the importance and urgency of this research. Gene therapies based on AAV vectors have been a revolutionary medical advancement in treating human genetic diseases. With a single dose, AAV-mediated gene therapies can confer long-term correction or abatement of disease for the lifetime of the patient.

DENIAL OF APPLICATIONS WITHOUT SCIENTIFIC REVIEW

56. The University of Massachusetts has had multiple grant applications submitted in response to NIH-issued Notices of Funding Opportunities ("NOFO"). NIH subsequently withdrew several of those NOFOs, summarily denying related applications to study section review. This has resulted in at least 10 grant applications submitted by the University of Massachusetts that were denied without assessment based on scientific merit, including:

    a. "The impact of ovarian hormones on sleep dependent emotional memory in younger and older adult women," submitted under PAR-23-271.

    b. "Understanding the role of morphology and the extracellular matrix in radial glial differentiation and polarity within cortical brain organoids," submitted under PAR-23-271.

    c. "Understanding socio-cultural and family-level biobehavioral processes that are associated with Hispanic/Latinx youth mental health disparities," submitted under PAR-21-358.

    d. "Advancing sexual orientation-based metabolic health disparities research among women through data integration," submitted under PAR-24-077.

HARMS

57. The impact of the NIH's capricious blockade of the grant process has already had, and will continue to have, a devastating impact. Examples of the irreparable harm already caused and continuing to be caused includes, but is not limited to: significant damages to the career progression of students and faculty who depend on the financial support from these grants and who have had no notice and therefore no time to seek alternatives; individuals in the community who would have participated in these sponsored projects who are deprived of the benefits from the research—for instance, individuals at risk from COVID-19 exposure or individuals in need of dementia care, *see* ¶ 18, *supra*; extreme disruption to the research record of students and young faculty, impairing them from establishing careers in biomedical research; and the development of new understandings and treatments.

58. In the last decade, UMass Amherst has hired 37 new faculty members and 28 staff members in Life Sciences through strategic investment in the Institute for Applied Life Sciences, established with an investment of $95 million from the Commonwealth and more than $50 million from the University of Massachusetts for the Institute for Applied Life Sciences' facilities and equipment. The Institute relies on a portion of the NIH funding provided to the campus for grants associated with the Institute.

59. There are 30 Life Sciences Core Facilities with professional staffing at UMass Amherst; in total, there are 90 such Core Facilities across the University of Massachusetts. To operate its Core Facilities, UMass Amherst purchases necessary and sophisticated scientific equipment. This equipment, and the professional staff who work there, are administered by UMass Amherst's Institute for Applied Life Sciences. Running the Core Facilities requires significant capital investments and also requires continuous funding for the operations that

support hundreds of researchers on not only the UMass Amherst campus, but across all University of Massachusetts campuses as well as small businesses in Massachusetts. Funding for the debt service on the University of Massachusetts' capital investment, staffing, and operations relies in part on NIH funding as well as funding from other federal agencies. The NIH funding slowdown will likely cause UMass Amherst to reduce the scope and support for Core Facilities.

60. Several research projects with a start date of April 1, 2025, with fundable scores for scientific merit, have not received a funding decision by NIH, discussed *supra*. Many of these projects underwent advisory council review *months ago*. For example, one such project has needed to acquire neurodegenerative mouse models, breed the animals, them age them to the point that neurogenerative phenotypes begin to appear, several researchers were hired to begin this process. *See* ¶¶ 45-50, *supra*. The unprecedented delay in rendering a funding decision for this project required the PI to begin these steps prior to receipt of the NOA or else compromise the efficiency and integrity of the entire project. Until that decision is rendered, UMass Amherst has chosen to absorb the costs of these expenses in the interim; the alternative would be to scrap the entire project, relegating to waste all preparatory steps taken and the time and resources that would have been directed toward more fruitful projects had a timely decision been made by NIH.

61. The pursuit of alternative sources of funding as a response to the harms caused by the delay in evaluating applications is not a practical solution. PIs typically learn of their fundable scores within a few months of the start date of their project; after receiving such a score, they begin to take the expensive preparations necessary to ensure a timely start. Applications for funding from alternative sources typically take 12-18 months and are not a practical method

of reducing waste and harm caused by an unprecedented short-notice failure to fund in the days leading up to that start date.

62. The NIH funding blockade has also significantly impacted the University of Massachusetts in numerous other ways, including but not limited to:

a. The University of Massachusetts has been forced to reduce graduate admissions via rescission of accepted applications. UMass Chan Medical School has reduced acceptances to UMass Chan Medical School's PhD program in Biomedical Sciences from 80 to approximately 12, forcing it to rescind offers to the majority of accepted applicants. UMass Amherst has reduced graduate admissions to doctoral programs by 29% from last year, a loss of 285 admission spots (reducing from 997 to 712), and rescinded offers of financial support (including salary and tuition) to many of those admitted. The reductions are largest in programs that rely significantly on NIH support, including:

	Fall 2024	Fall 2025	% Change
College of Engineering	123	102	-17%
College of Natural Sciences	405	273	-33%
College of Information & Computer Sciences	147	83	-44%
School of Public Health & Health Sciences	62	29	-53%

b. The termination of multiple active grants and the reduction of size of the incoming classes of graduate students also negatively affects the scientific integrity, efficiency, and cost of ongoing research projects that still have funding. First-year students rotate through three different labs before

attaching to one project. These students provide multiple research projects with access to qualified scientific professionals at relatively low costs. Reduction of this pool, both immediately and necessarily in the future due to enrollment cuts, simultaneously reduces the access of every research project to this pool of qualified candidates while increasing the cost of whatever research assistants take their place.

c. UMass Amherst has announced that it will provide Emergency Funding to cushion the immediate impact of interrupted federal funding. This is not to replace federal funding but to maintain salary support temporarily and give students and other trainees a chance to finish their graduate programs and/or find alternative sources of funding, or employment. UMass Amherst is diverting funds from other important needs such as deferred maintenance and strategic investments to provide this emergency support.

d. UMass Chan Medical School has ongoing financial obligations to support its research facilities. Part of these costs were covered by the indirect cost payments from NIH grants. The termination of several of those grants and the delay in securing funding for future grants has forced the school to dedicate an increased amount of its funds to maintain those facilities, coming at the expense of suspending ongoing faculty searches, rescinding outstanding offers to graduate students, and furloughing hundreds of personnel across all areas of employment. These restrictions in turn have slowed the school's ability to perform critical research in multiple areas, including gene therapy for life-threatening diseases that affect children

and research on treatments for pediatric brain tumors and ALS, among others.

63. The NIH funding blockade is also likely to cause future harm to UMass Amherst in numerous other ways, including but not limited to:

a. The delays in the NIH's grant approval process have already directly resulted in irreparable harm by reducing the number of applicants who can be accepted as doctoral students at UMass Amherst to do the research associated with the delayed grants. If the delays in the NIH grant approval process continue, the future of these prospective students, their desired programs of study, and the critical research they would be performing will be irreparably and irretrievably damaged. Furthermore, because the delays are so widespread nationally, opportunities at other universities will also be curtailed.

b. UMass Amherst is concerned that further recruiting of doctoral students, postdoctoral researchers, faculty and staff will be negatively impacted by diminished funding and by harm to the institution's reputation arising from limiting graduate admissions and rescinding financial offers of support to doctoral students.

c. UMass Amherst is also concerned about reduced ability to meet existing obligations to repay bond funds used to construct research facilities and

that rating agencies may reduce the University bond rating[4] making it more expensive to build research facilities in the future.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on April 3, 2025, at Westborough, Massachusetts.

/s/ *Denise Barton*
Denise Barton
Chief Deputy General Counsel
University of Massachusetts, Office of the General Counsel
50 Washington Street
Westborough, MA 01581

[4] On March 19, Moody's Ratings, "dropped its outlook for higher education in 2025 to negative from stable amid the Trump administration's financial attacks on the sector." *See* https://www.highereddive.com/news/moodys-negative-outlook-higher-ed-trump-cuts/743014/; *see also* https://www.forbes.com/sites/michaeltnietzel/2025/03/19/moodys-lowers-higher-ed-outlook-to-negative-citing-trump-policies/.

EXHIBIT A

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R01MH134176
Federal Award Date
06/26/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF MASSACHUSETTS
101 COMMONWEALTH AVE
AMHERST, MA 01003

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1043167352B5

4. Employer Identification Number (EIN)
043167352

5. Data Universal Numbering System (DUNS)
153926712

6. Recipient's Unique Entity Identifier
VGJHK59NMPK9

7. Project Director or Principal Investigator
Sarah L Goff, MD (Contact)

sgoff@umass.edu
413-545-7467

8. Authorized Official
SARA SANTOS
SARASANTOS@UMASS.EDU
413-545-0699

Federal Agency Information

9. Awarding Agency Contact Information
CHRISTOPHER MIN-SIK Oh

NATIONAL INSTITUTE OF MENTAL HEALTH
chris.oh@nih.gov
(301) 480-1764

10. Program Official Contact Information
Jennifer Humensky

NATIONAL INSTITUTE OF MENTAL HEALTH
jennifer.humensky@nih.gov
301-480-1265

Federal Award Information

11. Award Number
5R01MH134176-02

12. Unique Federal Award Identification Number (FAIN)
R01MH134176

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Effect of Medicaid Accountable Care Organizations on Behavioral Health Care Quality and Outcomes for Children

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/01/2024 **– End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$552,484
20 a. Direct Cost Amount	$377,949
20 b. Indirect Cost Amount	$174,535
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$552,484
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$552,484
26. Project Period Start Date 09/12/2023 **– End Date** 06/30/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,350,259

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Theresa A. Mercogliano

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 5R01MH134176-02

Principal Investigator(s):
Kimberley Lynn H Geissler, PHD
Sarah L Goff (contact), MD

Award e-mailed to: opam@umass.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $552,484 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MASSACHUSETTS AMHERST in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH134176. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Theresa A. Mercogliano
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$197,448
Fringe Benefits	$58,214
Personnel Costs (Subtotal)	$255,662
Consultant Services	$5,000
Materials & Supplies	$934
Travel	$5,000
Other	$14,200
Subawards/Consortium/Contractual Costs	$94,153
Publication Costs	$3,000
Federal Direct Costs	$377,949
Federal F&A Costs	$174,535
Approved Budget	$552,484
Total Amount of Federal Funds Authorized (Federal Share)	$552,484
TOTAL FEDERAL AWARD AMOUNT	$552,484
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$552,484

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$552,484	$552,484
3	$568,728	$568,728
4	$565,231	$565,231
5	$541,288	$541,288

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1043167352B5
Document Number: RMH134176A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027
MH	8022585	$552,484	$568,728	$565,231	$541,288

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 82-SEEC / **OC**: 41025 / **Released**: 06/25/2024
Award Processed: 06/26/2024 12:19:46 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MH134176-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01MH134176-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH134176. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-

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discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 5R01MH134176-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-20-185 which can be referenced at: PA-20-185: NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed).

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **Baystate Medical Center, Inc.**
Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

DATA SHARING PLAN:
This award is subject to the data sharing guidance outlined in NOT-MH-19-033 and can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-mh-19-033.html. The recipient will adhere to the resource and data sharing plan. Dissemination of study data will be in accord with the Recipient's accepted data sharing plan. **Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing."** Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Complete NIMH data sharing terms and conditions can be found at https://nda.nih.gov/contribute/sharing-regimen.html. Instructions are available at http://grants.nih.gov/grants/rppr/index.htm. Complete guidelines on data sharing are available at https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/data-management-and-sharing-policy-overview#before.

DATA AND SAFETY MONITORING:
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

OTHER SUPPORT TIME COMMITMENT:
Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (I.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH

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support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MH134176-02

INSTITUTION: UNIVERSITY OF MASSACHUSETTS AMHERST

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$197,448	$197,448	$192,350	$192,350
Fringe Benefits	$58,214	$58,214	$58,110	$58,110
Personnel Costs (Subtotal)	$255,662	$255,662	$250,460	$250,460
Consultant Services	$5,000	$5,000	$5,000	$5,000
Materials & Supplies	$934	$3,184	$934	
Travel	$5,000	$5,000	$5,000	$5,000
Other	$14,200	$20,200	$25,500	$11,700
Subawards/Consortium/Contractual Costs	$94,153	$94,153	$94,153	$94,153
Publication Costs	$3,000	$3,000	$3,000	$3,000
TOTAL FEDERAL DC	$377,949	$386,199	$384,047	$369,313
TOTAL FEDERAL F&A	$174,535	$182,529	$181,184	$171,975
TOTAL COST	$552,484	$568,728	$565,231	$541,288

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	61.5%	62.5%	62.5%	62.5%
F&A Cost Base 1	$283,796	$292,046	$289,894	$275,160
F&A Costs 1	$174,535	$182,529	$181,184	$171,975

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EXHIBIT B

From: Bulls, Michelle G. (NIH/OD) [E]
To: Alene Denson
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:38:13 PM
Attachments: image002.png

You don't often get email from michelle.bulls@nih.gov. Learn why this is important

National Institutes of Health
Office of Extramural Research

3/21/2025

Alene Denson
University Of Massachusetts Amherst
ADENSON@UMASS.EDU

Dear Alene Denson:

Effective with the date of this letter, funding for Project Number 3R01MH134176-02S1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/16/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9]

See 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT C

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R33HD107988
Federal Award Date
08/12/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
55 LAKE AVE N
WORCESTER, MA 01655

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1043167352A1

4. Employer Identification Number (EIN)
043167352

5. Data Universal Numbering System (DUNS)
603847393

6. Recipient's Unique Entity Identifier
MQE2JHHJW9Q8

7. Project Director or Principal Investigator
Bo Wang, PHD (Contact)
Professor
Bo.Wang@umassmed.edu
508-421-1419

8. Authorized Official
Melissa Siegel Spragens

Federal Agency Information

9. Awarding Agency Contact Information
Marianne Galczynski
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
marianne.galczynski@nih.gov
(240) 276-5588

10. Program Official Contact Information
FRANKLIN WILLEM Yates

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
franklin.yates@nih.gov
240-890-3679

Federal Award Information

11. Award Number
5R33HD107988-04

12. Unique Federal Award Identification Number (FAIN)
R33HD107988

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2024 **– End Date** 07/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$2,790
20 a. Direct Cost Amount	$2,162
20 b. Indirect Cost Amount	$628
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$278,952
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$278,952
26. Project Period Start Date 08/13/2021 **– End Date** 07/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$562,627

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Frances Petti

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY DEVELOPMENT AWARD
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R33HD107988-04 REVISED

Principal Investigator(s):
Karen MacDonell, PHD
NITTAYA PHANUPHAK, MD
Bo Wang (contact), PHD

Award e-mailed to: Research.Funding@umassmed.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of $2,790 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Univ of Mass Chan Medical School in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R33HD107988. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Frances Petti
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$40,836
Fringe Benefits	$17,290
Personnel Costs (Subtotal)	$58,126
Consultant Services	$30,000
Materials & Supplies	$2,356
Travel	$2,500
Subawards/Consortium/Contractual Costs	$123,207
Federal Direct Costs	$216,189
Federal F&A Costs	$62,763
Approved Budget	$278,952
Total Amount of Federal Funds Authorized (Federal Share)	$278,952
TOTAL FEDERAL AWARD AMOUNT	$278,952
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$2,790

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$278,952	$278,952
5	$273,994	$273,994

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1043167352A1
Document Number: RHD107988B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025
HD	8014710	$278,952	$273,994

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: MPIDB-FY / **OC**: 41025 / **Released**: 08/11/2024
Award Processed: 08/12/2024 12:06:03 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R33HD107988-04 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R33HD107988-04 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R33HD107988. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see

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https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R33HD107988-04 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION- Restore Reduction
This revised award restores the 1% administrative reduction applied to the previously issued Notice of Award.

The previous terms and conditions of award remain in effect as stated below.

*****

Clinical Trial - Dissemination Policy
The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **12/03/2020** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov n/ot later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

Clinical Trial - Risk Assessment
Clinical Trial Study/Studies: **361607**

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The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **MEDIUM** risk requiring increased oversight by NICHD. An update on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones will be due **once a year (generally halfway through the budget period)** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Foreign Component

This award includes foreign component at the following site(s): Institute of HIV Research and Innovation in THAILAND

Notice Of Funding Opportunity

This award is subject to the requirements indicated in **PAR19-376**, which are hereby incorporated by reference. See the NIH Funding site for more information.

Human Subjects

For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Multiple Principal Investigator

The recipient must follow the Multiple Principal Investigator Leadership Plan included in the JIT dated 06/03/2021 and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R33HD107988-04 REVISED

INSTITUTION: Univ of Mass Chan Medical School

Budget	Year 4	Year 5
Salaries and Wages	$40,836	$38,794
Fringe Benefits	$17,290	$16,426
Personnel Costs (Subtotal)	$58,126	$55,220
Consultant Services	$30,000	$30,000
Materials & Supplies	$2,356	$1,734
Travel	$2,500	$2,500
Subawards/Consortium/Contractual Costs	$123,207	$124,159
TOTAL FEDERAL DC	$216,189	$213,613
TOTAL FEDERAL F&A	$62,763	$60,381

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TOTAL COST	$278,952	$273,994

Facilities and Administrative Costs	Year 4	Year 5
F&A Cost Rate 1	67.5%	67.5%
F&A Cost Base 1	$92,982	$89,454
F&A Costs 1	$62,763	$60,381

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EXHIBIT D

From: Gardiner, Karen
To: Miarecki, Amy
Subject: FW: Grant Termination Notification
Date: Friday, March 21, 2025 3:24:40 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:35 PM
To: Research Funding <Research.Funding@umassmed.edu>
Subject: Grant Termination Notification



3/21/2025

Spragens, Melissa Siegel
Univ Of Massachusetts Med Sch Worcester
research.funding@umassmed.edu

Dear Spragens, Melissa Siegel:

Effective with the date of this letter, funding for Project Number 5R33HD107988-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is

incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT E

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R34MH124081
Federal Award Date
06/19/2023

Recipient Information

1. Recipient Name
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
55 LAKE AVE N

WORCESTER, MA 01655

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1043167352A1

4. Employer Identification Number (EIN)
043167352

5. Data Universal Numbering System (DUNS)
603847393

6. Recipient's Unique Entity Identifier
MQE2JHHJW9Q8

7. Project Director or Principal Investigator
Bo Wang, PHD (Contact)
Professor
Bo.Wang@umassmed.edu
508-421-1419

8. Authorized Official
CHEIKH CAMARA
Cheikh.Camara@umassmed.edu
508-856-8126

Federal Agency Information

9. Awarding Agency Contact Information
Maggie C. Paolini
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
maggie.paolini@nih.gov
301-443-2746

10. Program Official Contact Information
Susannah Allison

NATIONAL INSTITUTE OF MENTAL HEALTH
allisonsu@mail.nih.gov
240-627-3861

Federal Award Information

11. Award Number
5R34MH124081-03

12. Unique Federal Award Identification Number (FAIN)
R34MH124081

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Adapting effective mhealth interventions to improve uptake and adherence of the HIV pre- exposure prophylaxis (PrEP) in Thai young MSM

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2023 **– End Date** 06/30/2024	
20. Total Amount of Federal Funds Obligated by this Action	$202,639
20 a. Direct Cost Amount	$167,000
20 b. Indirect Cost Amount	$35,639
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$202,639
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$202,639
26. Project Period Start Date 07/01/2021 **– End Date** 06/30/2024	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$671,459

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Maggie C. Paolini

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 5R34MH124081-03

Principal Investigator(s):
NITTAYA PHANUPHAK, MD
Bo Wang (contact), PHD

Award e-mailed to: Research.Funding@umassmed.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $202,639 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Univ of Mass Chan Medical School in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R34MH124081. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Maggie C. Paolini
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$167,000
Federal F&A Costs	$35,639
Approved Budget	$202,639
Total Amount of Federal Funds Authorized (Federal Share)	$202,639
TOTAL FEDERAL AWARD AMOUNT	$202,639
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$202,639

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$202,639	$202,639

Fiscal Information:

Payment System Identifier:	1043167352A1
Document Number:	RMH124081A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023
MH	8472592	$202,639

NIH Administrative Data:
PCC: 9A-ASPA / **OC**: 41025 / **Released**: Paolini, Maggie 06/14/2023
Award Processed: 06/19/2023 12:05:31 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R34MH124081-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R34MH124081-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

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references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R34MH124081. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at:
http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures

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reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-

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proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 5R34MH124081-03

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:

This award has been made in response to the application submitted under the Funding Opportunity Announcement PA20-141 which can be referenced at: PA-20-141: Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (R34 Clinical Trial Optional) (nih.gov)

CONSORTIUM / CONTRACTUAL COSTS:

This award includes funds for consortium activity with **HIV Research and Innovation, Bangkok, Thailand, Wayne State University, University of California, San Francisco**. Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

PARTICIPANT RECRUITMENT - MILESTONES:

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 05/10/2021. It is expected that **120 o**f the **120** total projected participants will be recruited by **08/01/2023**. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls

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significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

GCP TRAINING:
NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated 09/08/2020 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:
This grant is expected to involve a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards cited in NOT-MH-19-027. Each RPPR submitted should include copies of all DSMB reports in RPPR Section G.1 since the last annual award. The recipient is also reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the NIMH Reportable Events Policy cited in NOT-MH-19-027, as appropriate.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R34MH124081-03

INSTITUTION: Univ of Mass Chan Medical School

Budget	Year 3
TOTAL FEDERAL DC	$167,000
TOTAL FEDERAL F&A	$35,639
TOTAL COST	$202,639

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	67.5%
F&A Cost Base 1	$52,798

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F&A Costs 1	$35,639

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EXHIBIT F

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R34MH124081
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
55 LAKE AVE N
WORCESTER, MA 01655

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1043167352A1

4. Employer Identification Number (EIN)
043167352

5. Data Universal Numbering System (DUNS)
603847393

6. Recipient's Unique Entity Identifier
MQE2JHHJW9Q8

7. Project Director or Principal Investigator
Bo Wang, PHD (Contact)
Professor
Bo.Wang@umassmed.edu
508-421-1419

8. Authorized Official
CHEIKH CAMARA
Cheikh.Camara@umassmed.edu
508-856-8126

Federal Agency Information

9. Awarding Agency Contact Information
Maggie C. Paolini
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
maggie.paolini@nih.gov
301-443-2746

10. Program Official Contact Information
Susannah Allison

NATIONAL INSTITUTE OF MENTAL HEALTH
allisonsu@mail.nih.gov
240-627-3861

Federal Award Information

11. Award Number
5R34MH124081-03

12. Unique Federal Award Identification Number (FAIN)
R34MH124081

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Adapting effective mhealth interventions to improve uptake and adherence of the HIV pre- exposure prophylaxis (PrEP) in Thai young MSM

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/01/2023 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$202,639
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$202,639
26. Project Period Start Date 07/01/2021 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$671,459

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Theresa R. Jarosik

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 5R34MH124081-03 REVISED

Principal Investigator(s):
NITTAYA PHANUPHAK, MD
Bo Wang (contact), PHD

Award e-mailed to: Research.Funding@umassmed.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Univ of Mass Chan Medical School in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R34MH124081. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Theresa R. Jarosik
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Federal Direct Costs	$167,000
Federal F&A Costs	$35,639
Approved Budget	$202,639
Total Amount of Federal Funds Authorized (Federal Share)	$202,639
TOTAL FEDERAL AWARD AMOUNT	$202,639

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$202,639	$202,639

Fiscal Information:
Payment System Identifier: 1043167352A1
Document Number: RMH124081A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
MH	8472592	$202,639

NIH Administrative Data:
PCC: 9A-ASPA / **OC**: 41025 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:03:03 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R34MH124081-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R34MH124081-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

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This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R34MH124081. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 5R34MH124081-03 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION -TERMINATION

It is the policy of NIH not to prioritize research activities based on diversity, equity, and inclusion ("DEI") no longer effectuates agency priorities. Therefore, this project is terminated. The UNIVERSITY OF MASSACHUSETTS may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you

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mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

SUPERSEDES NOTICE OF AWARD ISSUED 10/16/2024

NO-COST EXTENSION:

This revised award provides a first no-cost extension through 6/30/2025 in accordance with the recipient's request dated 9/26/2024. The project period end date has been adjusted accordingly. In extending the final budget period, the recipient agrees to update all required certifications, including human subjects and animal welfare, in accordance with applicable regulations and policy.

THIS REVISED AWARD SUPERSEDES THE NOTICE OF AWARD ISSUED ON 6/19/2023. THE FOLLOWING TERMS & CONDITIONS REMAIN IN EFFECT.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA20-141 which can be referenced at: PA-20-141: Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (R34 Clinical Trial Optional) (nih.gov)

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **HIV Research and Innovation, Bangkok, Thailand, Wayne State University, University of California, San Francisco**. Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 05/10/2021. It is expected that **120 o**f the **120** total projected participants will be recruited by **08/01/2023**. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

GCP TRAINING:
NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated 09/08/2020 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21

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calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:
This grant is expected to involve a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards cited in NOT-MH-19-027. Each RPPR submitted should include copies of all DSMB reports in RPPR Section G.1 since the last annual award. The recipient is also reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the NIMH Reportable Events Policy cited in NOT-MH-19-027, as appropriate.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R34MH124081-03 REVISED

INSTITUTION: Univ of Mass Chan Medical School

Budget	Year 3
TOTAL FEDERAL DC	$167,000
TOTAL FEDERAL F&A	$35,639
TOTAL COST	$202,639

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	67.5%
F&A Cost Base 1	$52,798
F&A Costs 1	$35,639

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EXHIBIT G

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R03MH130275
Federal Award Date
06/21/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
55 LAKE AVE N
WORCESTER, MA 01655

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1043167352A1

4. Employer Identification Number (EIN)
043167352

5. Data Universal Numbering System (DUNS)
603847393

6. Recipient's Unique Entity Identifier
MQE2JHHJW9Q8

7. Project Director or Principal Investigator
Feifan Liu, PHD (Contact)
Assistant Professor
feifan.liu@umassmed.edu
774-455-4586

8. Authorized Official
Lindsey M Demerrit
lindsey.demeritt@umassmed.edu
407-919-9556

Federal Agency Information

9. Awarding Agency Contact Information
Marla Dominguez
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
marla.dominguez@nih.gov

10. Program Official Contact Information
Lori Scott-Sheldon

NATIONAL INSTITUTE OF MENTAL HEALTH
lori.scott-sheldon@nih.gov

Federal Award Information

11. Award Number
5R03MH130275-02

12. Unique Federal Award Identification Number (FAIN)
R03MH130275

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Applying Deep Learning for Predicting Retention in PrEP Care and Effective PrEP Use among Key Populations at Risk for HIV in Thailand

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/01/2024 **– End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$76,214
20 a. Direct Cost Amount	$51,497
20 b. Indirect Cost Amount	$24,717
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$76,214
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$76,214
26. Project Period Start Date 07/01/2023 **– End Date** 06/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$162,404

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Rita Sisco

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

SMALL RESEARCH GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 5R03MH130275-02

Principal Investigator(s):
Rena Janamnuaysook
Feifan Liu (contact), PHD
NITTAYA PHANUPHAK, MD

Award e-mailed to: Research.Funding@umassmed.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $76,214 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Univ of Mass Chan Medical School in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R03MH130275. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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Sincerely yours,

Rita Sisco
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$51,497
Federal F&A Costs	$24,717
Approved Budget	$76,214
Total Amount of Federal Funds Authorized (Federal Share)	$76,214
TOTAL FEDERAL AWARD AMOUNT	$76,214
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$76,214

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$76,214	$76,214

Fiscal Information:
Payment System Identifier: 1043167352A1
Document Number: RMH130275A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MH	8472592	$76,214

NIH Administrative Data:
PCC: 9A-ASPI / **OC**: 41025 / **Released**: 06/20/2024
Award Processed: 06/21/2024 12:32:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R03MH130275-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

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Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

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NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 5R03MH130275-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA20-200 which can be referenced at: https://grants.nih.gov/grants/guide/pa-files/PA-20-200.html

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **Institute of HIV Research and Innovation, Thailand.** Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

RECIPIENT RELYING ON SUBAWARDEE'S IRB APPROVAL:
This award acknowledges that Institute of HIV Research and Innovation, Thailand has accepted the responsibility for the IRB review and approval of this application. University of Massachusetts

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continues to be responsible for all human subjects research conducted under the award, and must provide oversight and monitoring of all human subjects research activities commensurate with its legal role and responsibilities to assure appropriate protections for human subjects in research. This includes, but is not limited to, ensuring that all institutions engaged in non-exempt human subject research conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Each institution engaged in the HHS-supported non-exempt human subjects research must hold or obtain an applicable OHRP-approved Federal Wide Assurance (FWA) as described in (45 CFR 46.103(a)). Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

DATA AND SAFETY MONITORING: Study ID 457247
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

OTHER SUPPORT TIME COMMITMENT:
Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (I.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R03MH130275-02

INSTITUTION: Univ of Mass Chan Medical School

Budget	Year 2
TOTAL FEDERAL DC	$51,497
TOTAL FEDERAL F&A	$24,717
TOTAL COST	$76,214

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	67.5%
F&A Cost Base 1	$36,618
F&A Costs 1	$24,717

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EXHIBIT H

From: Miarecki, Amy
To: Miarecki, Amy
Subject: FW: Grant Termination Notification
Date: Friday, March 21, 2025 3:41:32 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:31 PM
To: Camara, Cheikh <Cheikh.Camara@umassmed.edu>
Subject: Grant Termination Notification

3/21/2025

Cheikh Camara
Univ Of Massachusetts Med Sch Worcester
cheikh.camara@umassmed.edu

Dear Cheikh Camara:

Effective with the date of this letter, funding for Project Number 5R03MH130275-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms

the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 13

In the UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs*, v. ROBERT F. KENNEDY, JR, et al., *Defendants*.	No. 1:25-cv-_____

DECLARATION OF JASON A WILDER

I, Jason A. Wilder, hereby declare:

1. I am a resident of the State of Arizona. Since 2021, I have been employed by Northern Arizona University (NAU) as Vice President for Research. In addition to my current role, I have a Ph.D. in Biology and over 23 years of academic experience. I currently serve as Principal Investigator on an active award from NIH to NAU entitled "The Partnership for Native American Cancer Prevention"; this is an active five-year award (2024 to 2029) with a cumulative value of $6.4M.
2. As Vice President for Research at NAU, I have personal knowledge of the matters set forth below, or have knowledge of the matters based on my review of information and records provided to me by NAU employees, and believe that information to be true. In my capacity as Vice President of Research, I oversee NAU's total research portfolio, including all federally sponsored research grants to the university.
3. NAU was recently classified as a Carnegie R1 "Very High Research" university, which

is the highest classification in terms of overall research activity. In the fiscal year ending June 30, 2024, NAU had research expenditures in excess of $93M. Research at NAU encompasses a broad spectrum of focus areas that address pressing challenges and opportunities for Arizona and the nation, including vital health-related research routinely funded by the NIH, including pathogen genomics, microbiome studies, rural and community-focused health initiatives, and cancer-focused studies.

4. In federal fiscal year 2024, NAU managed 14 awards from NIH, totaling over $12.5 million.

5. As of the date of this declaration, we have received notification of termination of one NIH-funded award to NAU, entitled "Bridging Arizona Native American Students to Bachelor Degrees". This five-year $940K award has been terminated after its 4th year of activity and the final 5th year of activity ($207K) will not be supported. This award funds a unique transfer program of students from 2-year associates degree programs at Coconino Community College (CCC) to 4-year baccalaureate degree programs at NAU. Program activities for students currently supported by this program will cease prematurely, putting the likelihood of transferring to NAU and completion of a baccalaureate degree at risk for these students.

6. As of the date of this declaration, one of NAU's NIH-funded projects is delayed due to the failure of NIH to issue a Notice of Award; this notice authorizes funding from one grant award period to the next as specified in the original grant proposal and is non-competitive. This delay means that the university must rely on other funds to support the project as we wait for a Notice of Award to be issued. This interruption creates a risk that we may lose employees with specialized expertise on a project that may later be resumed,

and may affect the progress of students in their degree programs.

7. NAU has 34 proposals with a cumulative value of $47M that have been submitted to NIH but for which we have not received a response. These proposals include both research grants and training grants. The latter impact the number of graduate students we can support in NAU degree programs because these awards fund Graduate Assistantships (GAs). These GA positions cover tuition and fees for students and modest stipends. NIH-supported GA positions support our PhD programs in Interdisciplinary Health, Informatics, and Biology.

8. The nature of scientific research, including health research, is that it is often cumulative, with research teams seeking subsequent grants to build on prior discoveries.

9. Ongoing research is also essential to the education of students, as the ability to participate in research projects led by experienced faculty is a core part of training them to be successful scientists in the future.

10. Any actions by NIH that delay or suspend funding for ongoing and proposed research may result in the loss of research materials or the need to re-do work that is underway, and thereby delay scientific discoveries and impair the competitiveness of the university's research program. Interruptions in the funding needed to continue research may also result in the loss of employees with specialized expertise, including on projects that may later be resumed, and may affect the progress of students in their degree programs.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 2nd day of April, 2025, in Flagstaff, Arizona.



Jason A. Wilder
Vice President for Research
Northern Arizona University

EXHIBIT 14

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF HALA MADANAT

I, Hala Madanat, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated here or have knowledge of the matters based on my review of information and records gathered by me and my colleagues at San Diego State University ("SDSU") and the San Diego State University Research Foundation ("SDSURF"). If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed as the Vice President for Research and Innovation of San Diego State University.

3. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

4. I am a Vice President and Distinguished Professor at San Diego State University, one of the 23 campuses in the California State University system. I have held the position of

Vice President for Research and Innovation since August 2022 after previously serving as Interim Vice President since 2020. I lead the university's research enterprise, fostering interdisciplinary collaboration, securing external funding and driving innovation. I work closely with other university administrators, campus academic deans and vice presidents, partners at other public universities that have agreements with SDSU, and also with the California State University system and nationwide associations to promote interdisciplinary work and research while driving innovative practices in support of faculty and student research, student engagement and community impact.

5. Under my leadership, SDSU has expanded its research capabilities, strengthened partnerships with industry and government and, in spring 2025, officially achieved R1 classification as a top-tier research institution in the United States.

6. As Vice President of Research and Innovation, I serve as the ex-officio Vice President of the Board of Directors of the SDSURF, which is the CSU auxiliary organization dedicated to supporting sponsored research at SDSU. In that capacity, I am responsible for the general focus of research activity and its integration with the academic mission of SDSU, oversight of the corporation's sponsored research functions as carried out by SDSURF's Chief Executive Officer, and ensuring SDSURF's support of the university vision for research and growth of the research enterprise.

7. Before my appointment as Vice President, I served as the Director of SDSU's School of Public Health, where I was also a Principal Investigator overseeing grant-funded research projects and other initiatives to enhance student success, faculty development and community engagement.

8. I joined the SDSU faculty in 2008 in the School of Public Health and later served as the chief research officer at SDSU, overseeing all aspects of the university's research endeavors, including SDSURF.

9. Prior to SDSU, I served in a faculty position at Utah Valley University and as a lecturer at Brigham Young University. As a university researcher, my expertise lies in chronic disease prevention and health disparities, with a particular focus on social determinants of health.

10. As a Principal Investigator who has been a faculty researcher for 19 years, my work has been funded by agencies such as the National Institutes of Health (NIH) and the U.S. Centers for Disease Control and Prevention, and I have published extensively in leading academic journals throughout my career. In total, I have served as the principal investigator, co-principal investigator or co-investigator on 20 grants totaling more than $45 million. I also have and continue to serve on numerous boards, including the San Diego Economic Development Corporation, California Institute for Regenerative Medicine, Connect San Diego, and Biocom California, among others.

Research Activity at SDSU

11. SDSU's statutory mission is to deliver high-quality undergraduate and graduate education, to drive research and innovation, and to contribute to workforce and economic development for the region and State of California. By equipping students with advanced knowledge and skills, SDSU fosters a well-educated workforce that drives economic development and strengthens California's leadership across industries.

12. SDSURF is an officially recognized auxiliary corporation of the California State University system, established in accordance with California Education Code sections 89900 et seq. to benefit the California State University system. Pursuant to the Operating Agreement

between California State University and SDSURF and in accord with Title 5 of the California Code of Regulations, section 42500, SDSURF performs certain functions critical to the mission of SDSU, including management of externally funded projects including research, workshops, conferences and institutes at SDSU. Federal research grants, including those issued by NIH, are managed by SDSURF.

13. SDSU's mission is a catalyst for regional and state economic growth, workforce development and social mobility and, in doing so, the university significantly contributes to California's economy, strengthens industries across disciplines and fields, and also enhances the state's competitive edge.

14. SDSU is a major public research institution, ranking as the No. 1 institution in the California State University system in federal research support, and as one of the top public research universities in California. SDSU employs 4,578 faculty and staff (not including the almost 3,300 student employees) who provide transformative experiences for nearly 40,000 students.

15. In Fiscal Year 2023-24, 373 San Diego State University researchers received 867 grants and contracts valued at $226,218,374 to support research, scholarship, community service, and creative activities. SDSURF employs approximately 3,800 employees annually in support of these activities.

16. SDSU offers bachelor's degrees in 97 areas, master's degrees in 87 fields and 25 doctoral programs. In addition to academic offerings at SDSU, SDSU Imperial Valley and SDSU Georgia, SDSU Global Campus offers online training, certificates and degrees in areas of study designed to meet the needs of students everywhere. Additionally, the development of SDSU Mission Valley, a mixed-use, medium-density development about 5 miles from SDSU's main

campus that is already home to Snapdragon Stadium and a river park, is currently under further development to expand the university's educational, research, entrepreneurial and technology transfer programs. Additional developments at SDSU Imperial Valley include the Sciences and Engineering Laboratories, a state-of-the-art teaching and research hub that will advance access to skill-building and career pathways to high-opportunity, high-demand jobs in California's Lithium Valley. Further, the SDSU Oaxaca Center for Mesoamerican Studies provides university faculty and students with classrooms, office space, outdoor spaces and administrative personnel to support new and ongoing programming, research and collaborations with colleagues and academic research partners in Oaxaca.

17. At SDSU, students participate in transformational research, international experiences, entrepreneurship initiatives, internships and mentoring, and a broad range of student life and leadership opportunities. SDSU is also a long-standing federally recognized Hispanic-Serving Institution (HSI) and is also a federally recognized Asian American and Native American Pacific Islander-Serving Institution (AANAPISI). In 2024, the university celebrated the milestone of reaching 500,000 alumni with the spring graduating class and, in 2025, was officially classified as an R1 research institution, the highest distinction given to doctoral universities in the Carnegie Classification of Institutions of Higher Education.

18. I am providing this declaration to explain the devastating impact of the abrupt cancellation of several grants awarded by NIH, as well as the disruptions caused by delays in the grant review and renewal process.

Reliance on NIH Funding

19. Cuts to NIH funding have significant and long-lasting impacts on faculty's careers, student training, and our ability to recover actual research costs and build physical

infrastructure to support scientific discovery. In addition, the cuts have a direct impact on the local San Diego economy and the broader U.S. global competitiveness in science and technology. Faculty rely on the funding from NIH to advance both scientific discovery and knowledge, train and support their students, and advance their careers.

20. The cuts to the NIH funding have a profound and often underappreciated impact on graduate students. Cuts to NIH funding, especially cuts without warning, have immediate and consequential impacts on our graduate students, who often live paycheck to paycheck, putting their housing and basic needs at risk. Graduate students, who are at the core of the research laboratories, rely heavily on NIH grants not only for resources to support research, but also for their own stipends, tuition support, and training programs. Our graduate students complete their training and enter our regional workforce as public-school teachers, nurses, speech-language pathologists, aerospace engineers, public health officials, physical therapists, and psychologists, to name a few.

21. Cuts to NIH funding not only affects our ability to provide critical labor needed in the community, but also limits access during training to research opportunities. With fewer resources available, labs will downsize or may halt projects altogether, reducing hands-on learning experiences that are essential for graduate and undergraduate training. This can significantly hinder students' scientific development and career advancement, especially in competitive fields that require technical expertise.

22. Additionally, the lack of funding can restrict travel to research conferences, collaborations, and networking opportunities — key elements that help students establish themselves professionally.

23. Importantly, current NIH funding cuts impact SDSU's ability to honor commitments already made to our graduate students when they joined our graduate programs. The funding insecurity created by the abrupt NIH cuts, terminations of grants, and delays in reviews of pending proposals and non-competing renewals results in an unstable environment with students either leaving their programs or having to find additional employment opportunities, thus reducing the time available to devote to their advanced study and training. This may lead to significantly delayed graduation times, increases in student loan debt, or decisions to abandon their graduate education altogether.

24. In fiscal year 2024, San Diego State University received funding either directly through the NIH or as a subrecipient on awards to other institutions from the NIH to support 197 projects, totaling $48,593,078.

25. San Diego State University receives NIH grants across a variety of institutes encompassed within the NIH, including the following:

National Institute of Arthritis/Musculoskeletal and Skin Diseases

National Institute on Minority Health and Health Disparities

National Cancer Institute

National Heart Lung and Blood Institute

National Institute of Child Health and Human Development

National Institute of Diabetes/Digestive and Kidney Diseases

National Institute on Deafness/Other Communication Disorders

National Institute of Aging

National Institute of Allergy and Infectious Diseases

National Institute of Environmental Health Sciences

National Institute of General Medical Sciences

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute on Drug Abuse

National Center for Complementary and Integrative Health

26. Through those NIH grants, SDSU funds 93 researchers as principal investigators or co-investigators.

27. The work done by SDSU researchers on NIH funded projects provides education and training in Public Health, Psychology, Speech, Language and Hearing, Social Work, Nursing, Exercise and Nutritional Sciences, Biology, Electrical Engineering, Mathematics, Chemistry, Child and Family Development, Special Education, Communications, and other programs.

28. SDSU provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the California economy.

29. SDSU has already begun a major construction project in Imperial Valley, with the support of the California State University system that, once completed, will bolster STEM teaching and research, particularly in the areas of life sciences. Another Life Sciences building to replace the current outdated structure on the main campus is in the planning and initial construction stages. This building will eventually house lecture spaces, teaching and research labs, and faculty offices.

30. The funding model for this active STEM infrastructure project relies on indirect cost recoveries from federal grants, which has long been an important source of predictable funding for universities to support the upkeep of research buildings, research laboratories and affiliated office spaces and to ensure safety measures, including environmental health and lab safety compliance, among many other benefits to both researchers and the university.

31. SDSURF owns, rents, or leases over 700,000 square feet of properties located adjacent to San Diego State University or in locations that support specific communities and participants in NIH funded research. These facilities provide much needed space to support NIH funded faculty that is not available on campus. The decrease in NIH funding and subsequent recovery of indirect costs has an immediate impact on the ability to maintain and allocate these facilities for research needs.

32. Federally supported STEM research drives innovation, improves quality of life and addresses nationwide and global challenges. Across disciplines, breakthroughs in STEM lead to real-world applications that benefit society. For example, research in biomedical engineering has led to life-saving technologies now widely used across medicine, such as MRI machines, prosthetic limbs and robotic surgery. Similarly, cancer research has improved early detection and treatment through targeted therapies, reducing mortality rates for many dozens of cancer types. Life sciences research is essential for addressing health crises, including infectious disease outbreaks, as well as chronic diseases like cancer and diabetes. Investments in fields such as cellular and molecular biology, genetics and evolutionary biology drive breakthroughs that deepen our understanding of living organisms. Cancer research benefits from diverse perspectives, improving the identification of genetic markers and mutations in specific populations, leading to more precise, personalized treatments.

Typical Timeline and Processes for NIH Grant Awards

33. The Sponsored Research Development office at SDSURF in collaboration with the Office of Research Advancement at SDSU works with researchers to submit grant applications and tracks grant applications and awards.

34. Based on my work as a faculty researcher for 19 years, Director of the School of Public Health for four years, and Vice President of Research and Innovation for almost five years, I have a strong understanding of the NIH grant process.

35. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

36. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

37. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to recommend a grant for funding is made. After

the advisory council meets, the relevant institute's Director typically approves the recommended grants, and a Notice of Award is promptly issued confirming the grant is funded.

The process for competitive renewals is very similar, but it is even more likely for a grant that has been funded in the past to be renewed.

38. Non-competing renewals for subsequent years funded on a multi-year project do not need to go back through the study section or advisory council for review. NIH typically only requires submission of a Research Performance Progress Report (RPPR). The report is reviewed by the program officer for performance and then forwarded to the grants office who issues the subsequent years funding Notice of Award.

39. As an auxiliary organization, SDSURF submits proposals, and accepts and administers NIH awards on behalf of SDSU. The budget process at SDSURF relies upon the NIH grant application, review, and approval cycle. Historically, SDSU has relied on grants being reviewed and scored within approximately nine months of submission. Non-competing renewals typically are issued within 60 to 90 days of submission of the RPPR and are considered guaranteed funding unless the Principal Investigator (PI) dies, is transferring to another institution, there is a question about research performance such as lack of ability to recruit sufficient subjects into a study, or in extremely rare cases, research misconduct.

40. Once a grant receives a score, SDSURF is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

41. Since late January 2025, the San Diego State University Research Foundation has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or otherwise not

scheduled, and grant application scoring has been significantly delayed. Only one supplement and three non-competing renewals have been issued to San Diego State University Research Foundation directly by NIH since the change of administration on January 21, 2025.

42. SDSURF has not received formal notice of changes for most of the non-competing renewals or new or competing renewals currently awaiting review. For others, SDSU has only been told that proposals are "paused" or "under review."

43. In a few instances, faculty who have been asked to serve on study sections, have received communication that the study section has been postponed and will be rescheduled at a later date.

44. As of April 1, 2025, the San Diego State University Research Foundation has 23 non-competing renewals totaling approximately $24.5 million pending action by the grants office to authorize the next segment of funding.

45. As of April 1, 2025, the San Diego State University Research Foundation has 34 new proposals and competing renewals totaling approximately $16 million awaiting NIH study section review.

46. As of April 1, 2025, the San Diego State University Research Foundation has 10 new proposals and competing renewals totaling approximately $3.2 million that received fundable scores, awaiting NIH advisory council and Notice of Award.

47. As of April 1, 2025, the San Diego State University Research Foundation has 5 proposals totaling approximately $1.7 million that received possibly fundable scores, and 4 proposals totaling $2.4 million with a lower probability of funding, awaiting NIH advisory council and possible Notice of Award.

48. As of April 1, 2025, the San Diego State University Research Foundation has an additional 65 new proposals and 2 non-competing renewals totaling approximately $6.7 million awaiting action by NIH, where we are proposed subrecipients on proposals submitted by other universities and organizations.

49. In total, San Diego State University has 143 new or competing proposals and non-competing renewals totaling approximately $54.4 million on hold due to NIH delays in proposal reviews.

Terminations of NIH Grants

50. As of April 1, 2025, San Diego State University Research Foundation has had at least 12 NIH grants terminated (including subawards from other universities) and one non-competing renewal issued -- a no-cost extension for three months in place of receipt of the final year of funding.

51. These terminations are attached hereto as Exhibits 1-12, and the action related to the non-competing renewal is attached hereto as Exhibit 13.

52. These terminations will result in the loss of approximately $6.5 million in research money to San Diego State University.

53. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer “effectuates agency priorities.” In my nearly 20 years working at San Diego State University, I have not seen this language previously used to cancel grants.

54. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, San Diego State University Research Foundation had not been given notice of any

opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was San Diego State University Research Foundation provided with any updated "agency priorities" with which its research must align.

55. In one case, the reason cited included reference to gender identity research, which in fact was not the subject of the research in question (see Exhibit 10). The research in question studies how societal mechanisms of systemic marginalization of sexual minorities (e.g., gay, lesbian, and bisexual individuals) give rise to urgent and sizeable mental health disparities in depression and suicide among sexual minority and heterosexual individuals in the United States. The project uses novel and state-of-the-science harmonization techniques to integrate ten large public health datasets totaling data from over 2.8 million individuals collected between 2008 and 2023 as a pivotal period that saw major societal change for sexual minorities in the US, to study how systemic oppression drives risk for depression and suicide among both sexual minority and heterosexual individuals.

56. The 12 programs terminated focused primarily on sexual minority populations or vaccine hesitancy and included the following:

- The Socioecology of Sexual Minority Stigma: Data Harmonization to Address Confounding Bias and Investigate Cross-Level Mental Health Effects
- NEXUS: A novel social network approach to intersectional stigma on HIV prevention among Latino MSM
- Cardiovascular Health of Sexual and Gender Minorities in the Hispanic Community Health Study/Study of Latinos (SGM HCHS/SOL)
- Suicide Prevention for Sexual and Gender Minority Youth

- Targeting Minority Stressors to Improve Eating Disorder Symptoms in Sexual Minority Individuals with Eating Disorders
- eSTEP: An integrated mHealth intervention to engage high-risk individuals along the full PrEP care continuum
- Minority Stress, Stimulant Use, and HIV among Sexual Minority Men: A Biopsychosocial Approach
- Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center - SLG and LYPS
- Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center - LYPS
- Proud to Quit (P2Q): A Person-centered mobile technology intervention for smoking cessation among transgender adults
- Faithful Response II: COVID-19 Rapid Test-to-Treat with African American Churches
- Increasing COVID-19 vaccine uptake among Latinos through a targeted clinical and community-behavioral intervention

57. In all cases, the notice of termination stated it was effective immediately with no consideration of impact on employees, on the need to transition clinical trial participants to other resources, loss of research data collected to date, or other lost investment by the federal government by early termination of ongoing grants.

Comparisons Across Administrations

58. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

59. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

60. The San Diego State University Research Foundation provides the staffing and administrative infrastructure to support the submission, administration, and financial compliance requirements of all externally funded grants and contracts.

61. For FY 2023-24, indirect cost recovery accounted for 70% of the resources received to fund the San Diego State University Research Foundation operating budget. Of the $33.2 million in indirect cost recovery earned, NIH accounted for $11.8 million or 36% of the total recovered costs.

62. Projecting how much indirect cost recovery will be received in future years is dependent on many factors including awards received to date, the number and requested amount of proposals submitted and waiting review by funding agencies, how much F&A is budgeted on awards in process, and the spending rate on active awards as indirect costs are recovered only as direct costs are expended.

63. Even though NIH has begun to resume scheduling of study sections, an entire quarter has been lost and it is unclear if sufficient study sections are being scheduled to make up for that delay. The uncertainty around terminations, issuance of non-competing renewals, and proposed reductions by NIH to indirect cost rates is making it extremely difficult to project a budget for FY 2025-26.

64. SDSU Research Foundation has already implemented a hiring chill on open positions for its core staff, is reducing non-mandatory travel and professional development, and will not be able to issue any cost-of-living increases impacting staff retention and turnover.

65. There is also an immediate impact on currently funded programs anticipating non-competing renewals. The SDSU Research Foundation normally would allow researchers to continue their research activities pending receipt of the Notice of Award for non-competing renewals through a prior authorization to spend process; however, SDSURF is unable to continue to provide the advance funding to offset ongoing activities given the uncertainty on whether non-competing renewals will be issued.

66. There are very limited institutional resources available given projected cuts to the state budget. As a result, program activities are being forced to stop activities, reduce project personnel, and shutdown programs with the same effect as if a termination notice had been issued.

67. In addition to grants received directly from NIH, San Diego State University Research Foundation receives a number of subawards from partnering universities, school districts, community health centers and other organizations that San Diego State University faculty collaborate with where those organizations are the prime recipient of funds from NIH.

68. The impact of the delay in funding is compounded by the similar delays experienced by our collaborating partners. These delays have forced us to implement bridge funding for faculty, drawing from limited discretionary resources. As of April 1, 2025, San Diego State University has reallocated funding originally intended to support postdoctoral employees to provide emergency bridge funding of approximately $1,000,000. This prevents the

use of these funds for any other purpose, including critically needed postdoctoral support on research of use for other planned improvements to our programs and research.

Effect on Public-Facing or State-Supported Programs

69. Our institution operates multiple programs funded jointly by NIH and the State of California, including community health clinics and research addressing health disparities. We are unable to finalize contracts with collaborators including other universities, school districts and community partners until federal funds are secured. We are also experiencing that from other entities unable to finalize contracts to us. That has led to considerable uncertainty and the inability to continue to provide funding to partners who do not have the resources to continue to provide the services usually funded through NIH grants.

Admissions, Training and Workforce Disruptions

70. San Diego State University uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level. Graduate students are guaranteed stipends for the duration of their training based on already awarded NIH grants and anticipated non-competing renewals.

71. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants). Currently, we have one F31 terminated impacting the pre-doctoral student's training timeline and funding.

72. We also currently have one international research faculty whose visa status is at risk due to termination of NIH awards supporting his research.

73. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of San Diego State University, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

74. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

75. Several proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

76. The delays have disrupted ongoing research, as well as setting back San Diego State University for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the use of limited research support funds provided to faculty by San Diego State University Research Foundation which are being used to keep certain research projects going. San Diego State University researchers have had to make decisions about which of these valuable programs to continue with these limited funds.

77. Some of these studies involve clinical trials for life-saving medications or procedures, and their closure would endanger the lives of patients.

78. For example, one of the projects terminated addresses the significant suicide and suicide attempt burden that exists among sexual minority youth and young adults. Research has

demonstrated this risk: making a suicide attempt in their lifetime is 4 to 5 times higher among sexual minority youth, and 8 to 9 times higher among transgender youth, when compared to the general public.

79. Of significant concern is the welfare of participants in this study. Currently, the project has over 85 active participants in the trial. The study participants are extremely vulnerable, ranging from age 15 to 29 years, and all identify as LGBTQ+. Participants all have a history of one or more suicide attempts with current suicidal ideation, and all participants assigned to the novel intervention have been promised six months of clinical and care intervention with regular risk assessments.

80. The termination of the grant midway through the clinical trial would cease the provision of essential suicide prevention care and regular suicide risk assessments, putting every active participant at very high risk for death or injury due to suicide.

81. The termination notice was received on Friday, March 21 and indicated the termination was effective immediately and that "costs resulting from financial obligations incurred after termination are not allowable." This abrupt termination provided no leeway for identifying and safely transitioning participants to alternative resources if any exist. Requests for guidance from the grants officer and from the National Institute of Mental Health Data and Safety Monitoring Board have gone unanswered.

82. Some of these studies had the potential to achieve breakthroughs, which would have advanced public health, and which will now not occur.

83. Delays have also disrupted community services, student opportunities, and public programs. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

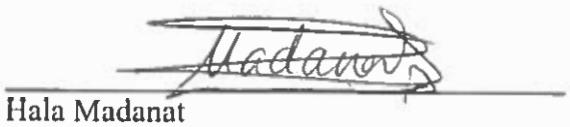
Conclusion

84. The abrupt terminations and irregularities in NIH grant funding are starting to have devastating consequences for institutional operations and planning, for researchers and students, and for study participants. With the current uncertainty surrounding NIH funding, early-career researchers and scientists are at risk of leaving STEM fields, thus weakening the pipeline of skilled talent.

85. The ongoing terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed this 2nd day of April, 2025, in Oakland, California.



Hala Madanat
Vice President for Research and Innovation
San Diego State University

EXHIBIT 15

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF GANESH RAMAN, Ph.D.

I, Ganesh Raman, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated here or have knowledge of the matters based on my review of information and records gathered by me and my colleagues at California State University ("CSU"). If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by California State University as the Assistant Vice Chancellor for Research

3. I submit this Declaration in support of the States' Motion for a Temporary Restraining Order.

Professional Background

4. I serve as the Assistant Vice Chancellor for Research at the California State University (CSU) Office of the Chancellor, a role I have held for the past eight years. I am the senior academic official responsible for the systemwide advancement, and administration of CSU's research and scholarly mission, overseeing 10 systemwide research consortia and numerous multi-campus institutes and centers.

5. Prior to joining CSU, I served as Deputy Vice Provost for Research at the Illinois Institute of Technology, where I also held a professorship in the Mechanical, Materials, and Aerospace Engineering Department. I began my career at NASA Glenn Research Center. I am internationally recognized for my research in aeroacoustics and flow control, with over 150 articles published in leading scientific journals and conference publications. I earned my Ph.D. in

Mechanical Engineering from Case Western Reserve University. I serve on the Board of Directors for the California Council on Science and Technology, California Life Sciences, and the Long Beach Accelerator. I also have the distinction of being elected Fellow of the American Society of Mechanical Engineers, American Institute of Aeronautics and Astronautics and the Royal Aeronautical Society, UK.

Research Activity in the CSU

6. The CSU is the largest four-year public university system in the United States and is the state's greatest producer of bachelor's degrees – awarding nearly 127,000 degrees each year – driving the economy in health care, agriculture, information technology, business, hospitality, life sciences, public administration, education, media and entertainment.

7. The CSU is responsible for providing higher education services to students across the state of California and throughout the United States. Consisting of 23 university campuses, nearly a dozen off-campus centers, and over 90 auxiliary organizations (several that are dedicated to sponsored research), the CSU educates more than 450,000 undergraduate and graduate students each year, and serves each of California's regions, from Humboldt to San Diego. The CSU offers more than 4,000 degree programs that align with workforce demands, including in health care and the sciences. CSU alumni make up a global network that is over four million strong. One in twenty Americans with a college degree earned it at the CSU. The CSU has more than 63,000 employees.

8. The CSU receives extensive federal funding for research. The CSU is distinctive for its experiential learning model, in which students work directly with faculty scholars on a broad array of research, scholarship and creative activities. These hands-on, immersive opportunities challenge students from all backgrounds to engage more deeply in their studies so

that they can discover new passions, career paths and to push beyond conventional career possibilities. Working alongside our students, the CSU's faculty researchers apply their immeasurable talents to expand knowledge in their fields to explore and develop cutting-edge fields and to build deep connections with the communities we serve to address the most pressing challenges.

9. A hallmark of CSU research is immersive student learning and discovery that addresses society's most urgent challenges, including those in health care, agriculture, water, fire prevention and cybersecurity. Undergraduate students who participate in faculty-mentored research are better prepared for future careers, graduate education and leadership roles that contribute to their respective communities.

10. Supplementing the individual campuses' research activities, the CSU also has 10 multi-campus research consortia that provide experiential learning opportunities for students, to prepare them for the workforce and address vital needs in California and across the country.

11. The research activities at CSU campuses are largely administered through non-profit, CSU auxiliary organizations. The California Education Code authorizes the establishment of legally distinct, non-profit auxiliary organizations whose sole purpose is to support the mission of the CSU. These CSU auxiliary organizations are operationally integral to CSU and are authorized to perform limited, essential functions as defined by the California Code of Regulations and the operating agreement between CSU and each auxiliary. Permissible functions include the administration of externally funded projects for CSU campuses, including all grants awarded by the NIH. (See Cal. Educ. Code §§ 89900 et seq.; 5 Cal. Code Regs. § 42500.)

12. As part of my responsibilities, I meet weekly with the Chief Research Officers at each of the 23 CSU universities and collect data and information regarding grant awards and

cancellations. The Chief Research Officers have reported significant delays in their dealings with NIH including delays in responding to grant award applications and general inquiries. Over the last month, the Chief Research Officers have reported that several grants awarded by the National Institutes of Health ("NIH") were abruptly cancelled. The Chief Research Officers also advised that several universities received a notice from NIH to cease all project activities associated with Undergraduate Research Training Initiative for Student Enhancement ("U-RISE"), which is funded through a grant from the National Institute of General Medical Sciences of NIH.

13. I provide this declaration to explain the devastating impact on the CSU system and its universities as the result of the abrupt cancellation of several grants awarded by NIH, and from the notice to cease all project activities associated with U-RISE.

Reliance on NIH Funding

14. CSU's budget relies on federal grant funding for its teaching and research mission, including, but not limited to, allocated funding for staffing, clinical trials, dissemination of results, public outreach, teaching and training students and others, equipment, and numerous other activities to fulfill its teaching and research mission, and serve the people of California and the United States.

15. Federal funds are CSU's single most important source of support for its research, accounting for more than 60% of CSU's total research awards.

16. For the fiscal year of July 1, 2023 to June 30, 2024 ("Fiscal Year 2024"), the total amount of all federal research awards to the CSU was $599,688,000.

17. During Fiscal Year 2024, the CSU expended nearly $90 million in NIH contract and grant funding to support approximately 250 projects across 18 of our universities, with the

total multi-year award funding in the hundreds of millions of dollars. With the current pace of grant terminations, CSU estimates this number will be dramatically reduced causing devastating impacts to CSU universities, faculty and students.

18. NIH research funding supports the United States' scientific competitiveness worldwide and enables the U.S. to be a global innovation leader. NIH research funding has led to scientific breakthroughs that have improved human health, including new treatments for cancer, diabetes, and declining death rates for heart attack and stroke. Funding also supports research in the biosciences and critical training grants to prepare the next generation of skilled workers.

19. Research funding is typically awarded through a competitive grant process, meaning that the annual research budget varies from year to year and depends on the success of CSU's researchers in these competitions. Federally supported research comes to CSU universities through CSU auxiliary organizations in a combination of both single- and multi-year awards. NIH awards are typically multi-year projects. CSU's universities collectively receive and expend millions of dollars annually in multi-year awards for their projects, centers, and institutes, and establish critical budget estimates for planning purposes in reliance on awarded grant funds.

20. CSU universities receive NIH grants across a variety of institutes and centers encompassed within the NIH.

21. NIH grants provide essential training and hands-on learning opportunities for CSU students. Grant opportunities also provided stipend and other funding to CSU students, staff and faculty. We estimate that the grant terminations and notice to cease project activities related to U-RISE directly will impact more than 150 students, over 100 faculty, as well as several staff members at CSU university campuses and will indirectly impact many others.

Terminations of NIH Grants

22. As part of my responsibilities, I meet weekly with the Chief Research Officers at each of the CSU universities and collect data regarding grant cancellations. Over the last month, the Chief Research Officers have reported several grant cancellations by NIH. Based on my review of the documentation shared with me as of April 1, 2025, I understand that NIH has terminated 17 grants, including at least 5 grants where a CSU university auxiliary was the primary grantee and at least 12 grants where the CSU university auxiliary serves as sub-grantee. Examples of these terminations, include, but are not limited to the following:

a. San Francisco State University, through The University Corporation – San Francisco State, received 3 termination notices of multi-year grants, one where it served as the primary awardee, and two where it serves as a sub-awardee. These terminations have resulted in a loss of at least $4,527,437.24 in budgeted research funding to the university.

b. San Diego State University, through San Diego State University Research Foundation, received 11 termination notices from the NIH for multi-year grants, including 4 where it served as the primary awardee and 7 where it serves as sub-awardee. These terminations have resulted in a loss of at least $1,575,880.62 in budgeted research funding to the university. These grants are described in greater detail in the accompanying declaration of Hala Madanat, Vice President for Research & Innovation, San Diego State University.

c. California State University, Fullerton, through CSU Fullerton Auxiliary Services Corporation, received one termination notice of a multi-year grant.

This termination has resulted in a loss of at least $853,583.14 in budgeted research funding to the university.

d. California State University, Northridge, through the University Corporation, received 2 sub-award termination notices of multi-year grants, resulting in the loss of at least $162,070.70 in budgeted research funding to the university.

e. San José State University, through The Tower Foundation of San José State University, has received one sub-award termination notice of a multi-year grant, resulting in the loss of at least $15,316 in budgeted research funding to the university.

23. The Notices of Award for the 17 grants described in Paragraph 22 are attached as Exhibits 1-17.

24. The Termination Notices for the 17 grants described in Paragraph 22 are attached as Exhibits 18-34.

25. These terminations alone will result in the combined loss of nearly $7 million in budgeted research funding to CSU universities. CSU estimates that the total number is much higher -- many CSU universities are currently closed for Spring recess and were not able to provide information regarding the impacts to them. Additionally, while preparing this declaration, I have been alerted to additional NIH grant cancellations that have not yet been accounted for or reflected in the total number of grant cancellations or in the calculation of financial impact.

26. As reflected in Exhibits 18-34, the termination notices sent by NIH to primary grantees at CSU universities followed a template that offered minimal explanation and merely stated that the research no longer “effectuates agency priorities.” I have spent many years

overseeing the administration of university research programs, including eight years at CSU. In my experience, grant terminations are rare and typically occur only in cases involving misconduct or fraud. Prior to 2025, I had never encountered a federal agency canceling a grant solely due to a shift in agency priorities.

27. The template termination notices also state that no corrective action can be taken to ensure the grant aligns with agency priorities. Based on my communications with the Chief Research Officers and review of the records provided, I understand that with respect to the terminated grants, prior to receipt of the termination notice, no CSU universities were provided with or informed of updated "agency priorities," nor were CSU universities given an opportunity to submit "corrected" grant materials to align with these new agency priorities.

28. The research grants awarded to CSU universities and terminated by NIH provided a direct benefit to the health of all Americans. For example, several terminated grants explored HIV prevention and outreach, including intervention to engage high-risk individuals along the full PrEP care continuum. While some interventions examine impact on specific communities, all efforts directly contribute to disease prevention in America. Mental health grants were terminated, including a grant providing suicide prevention services to sexual and gender minority youth. Notably, grant funding was terminated without any opportunity to bridge individuals at high-risk of suicide to new service providers. NIH also terminated a grant studying hazardous drinking and intimate partner aggression in a diverse sample of women and their partners.

U-RISE

29. Beginning on March 24, 2025 through April 1, 2025, at least 9 CSU universities reported that NIH sent a notice to the university to "cease project activities" related to the grant

program for Undergraduate Research Training Initiative for Student Enhancement ("U-RISE"). Notification letters to CSU universities concerning U-RISE are attached as Exhibits 35-43.

30. On April 2, 2025, two of these campuses advised that they received a notice from NIH terminating the U-RISE grant. The termination notices are attached as Exhibits 44 and 45. We anticipate that other CSU university campuses will receive similar termination notices.

31. U-RISE is funded through a grant from the National Institute of General Medical Sciences of NIH. The program aims to broaden perspectives in future scientific and biomedical research by identifying students interested in pursuing research as a career and by providing training opportunities to be competitive for entering graduate programs. This individual, student-centric approach for enhancing undergraduate education provide hands-on research training and mentorship for CSU students.

32. Students accepted into the U-RISE program receive trainee stipends as subsistence allowances to help defray living expenses during research training experiences. Trainee stipends are based on a full-time, 12-month appointment period and are built into the financial aid package of each student recipient.

33. Funding for the U-RISE program may also support student trainee travel expenses to attend and present at scientific meetings with their mentors, summer research experiences for extramural research, university personnel expenses and supplies.

34. At least 9 CSU universities received a notice from NIH stating that the university must "cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025."

35. As a result of this notice, the 9 CSU universities must immediately terminate stipends for students in the middle of the semester. Based on the data I have received to date, I am aware that 123 students are impacted. I have not received data from all 9 campuses and expect that many more CSU students will be impacted. As student financial aid packages account for U-RISE stipends, the mid-stream termination will cause direct and significant harm to participating students.

36. If additional university campuses receive termination notices and U-RISE funding is not restored, CSU estimates a loss of at least $5.5 million to CSU universities.

Comparisons Across Administrations

37. The recent activity by NIH is unprecedented. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

38. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

39. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations and Irreparable Harm

40. Reduced or cancelled NIH funding inflicts a multifaceted hardship upon regional public universities such as the CSU. Ongoing projects are forced to grind to a halt, wasting the valuable resources already expended and delaying scientific progress. Innovation is stifled, impeding the development of new medical treatments, technologies, and public health initiatives.

41. CSU must grapple with maintaining essential research infrastructure, facing financial strain that can lead to layoffs of researchers, staff, and support personnel. Recently

received grant terminations have placed CSU universities in an immediate state of review and analysis of non-cancellable financial obligations and mitigation efforts for each project. Mitigation efforts include identification of alternative fund sources both internal and external to the university, and employment placement. There are very limited institutional resources available given projected cuts to the state budget. As a result, program activities are being forced to stop activities, reduce project personnel, and shutdown programs.

42. The economic repercussions extend well beyond the university, affecting local businesses and industries reliant on university research activities, creating a ripple effect of economic decline.

43. The impact is particularly severe on training grants, such as the U-RISE program described above, and such programs are designed to train the next generation of the biomedical research workforce and offer crucial support to students. Abrupt funding cuts or pauses disrupt multi-year programs, leaving students in precarious situations mid-semester. The loss of stipends, scholarships, and living expenses creates significant financial hardship, forcing some to abandon their research and educational aspirations by dropping out of school. Reduced access to research opportunities and mentorship diminishes students' exposure to biomedical fields.

44. The impact of pausing or terminating NIH grants extends far beyond the direct research outcomes, creating a substantial, yet often obscured, disruption to student education and training. Traditional research grants, while primarily focused on project execution, typically provide essential funding for 2-5 students, enabling them to gain invaluable hands-on research experience and mentorship. Specialized training grants, like U-RISE, amplify this effect, directly supporting cohorts of 12-18 students, and fostering their development as future scientists. Furthermore, the indirect impact on student learning is substantial: funded professors

integrate their acquired knowledge and cutting-edge research findings into their curricula, enriching the educational experience for a much larger student body. Consequently, grant disruptions not only halt research progress but also impede the development of the next generation of researchers and limit the dissemination of vital scientific knowledge to a wider student audience.

45. The long-term consequences are profound. Scientific and economic progress slows, and the U.S. risks losing its global leadership in medical research and innovation. Delays in developing treatments and cures negatively impact public health. The abrupt nature of funding cuts inflicts emotional and academic distress upon students, damaging the pipeline of future researchers. The CSU, with limited resources, bears a disproportionate burden, exacerbating financial strain and competitive disadvantages.

Conclusion

46. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed this 2nd day of April, 2025, in Long Beach, California.

Ganesh Raman, Ph.D.
Assistant Vice Chancellor for Research
California State University

EXHIBIT 18

SDSU

Jennifer Sneed <jsneed@sdsu.edu>

FW: [EXT] Grant Termination Notification

1 message

Steve Torok <steve.torok@sdsu.edu> Fri, Mar 21, 2025 at 10:52 AM
To: sdsurf_federalimpacts@sdsu.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:35 AM
To: steve.torok@sdsu.edu
Subject: [EXT] Grant Termination Notification



3/21/2025

Steve Torok

San Diego State University

steve.torok@sdsu.edu

Dear Steve Torok:

Effective with the date of this letter, funding for Project Number 5R34MH129279-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective

action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 19

SDSU

Jennifer Sneed <jsneed@sdsu.edu>

Fwd: [EXT] Grant Termination Notification

1 message

SDSURF Awards <sdsurfawards@sdsu.edu> Fri, Mar 21, 2025 at 10:49 AM
To: SDSURF Federal Impact Responses <sdsurf_federalimpacts@sdsu.edu>

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <michelle.bulls@nih.gov>
Date: Fri, Mar 21, 2025 at 9:29 AM
Subject: [EXT] Grant Termination Notification
To: awards@foundation.sdsu.edu <awards@foundation.sdsu.edu>



3/21/2025

Torok, Steve

San Diego State University

awards@foundation.sdsu.edu

Dear Torok, Steve:

Effective with the date of this letter, funding for Project Number 5F31DA059345-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/17/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. [5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected

characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Pamela Fleming, Chief Grants Management Officer, NIDA

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 20

SDSU

Jennifer Sneed <jsneed@sdsu.edu>

Fwd: [EXT] Grant Termination Notification

1 message

SDSURF Awards <sdsurfawards@sdsu.edu> Fri, Mar 21, 2025 at 10:50 AM
To: SDSURF Federal Impact Responses <sdsurf_federalimpacts@sdsu.edu>

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <michelle.bulls@nih.gov>
Date: Fri, Mar 21, 2025 at 9:33 AM
Subject: [EXT] Grant Termination Notification
To: sdsurfawards@sdsu.edu <sdsurfawards@sdsu.edu>



3/21/2025

Steve Torok

San Diego State University

sdsurfawards@sdsu.edu

Dear Steve Torok:

Effective with the date of this letter, funding for Project Number 5R33MH120236-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 4/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. [5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected

characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 21

---------- Forwarded message ---------
From: **Renee Lechner** <rlechner@sdsu.edu>
Date: Fri, Mar 21, 2025 at 1:40 PM
Subject: Fwd: [EXT] SGM SOL Grant Termination Notice
To: SDSURF Federal Impact Responses <sdsurf_federalimpacts@sdsu.edu>

A termination notice for Dr. Gallos's award from the University of North Carolina Chapel Hill (fund 5A038E) was received this afternoon.

Renée Lechner
Interim Senior Director
Sponsored Research Administration
Sponsored Research Contracting & Compliance
rlechner@sdsu.edu
O: 619-594-4349

SDSU Research Foundation | foundation.sdsu.edu
5250 Campanile Drive | San Diego, CA 92182-1934
Twitter | Facebook | Instagram | LinkedIn
Service - Collaboration - Innovation - Diversity – Integrity



Your feedback counts! Did I help you today? Please take this brief service survey.

---------- Forwarded message ---------
From: **Desmon Fields** <dfields2@sdsu.edu>
Date: Fri, Mar 21, 2025 at 1:29 PM
Subject: Fwd: [EXT] SGM SOL Grant Termination Notice
To: Renee Lechner <rlechner@sdsu.edu>

Hi Renee,

We have just received this termination notice in regards to Dr. Gallo's award with UNC Chapel Hill Fund #5A038E.

Thank you,

Desmon Fields | Analyst
Sponsored Research Contracting and Compliance

dfields2@sdsu.edu

SDSU Research Foundation | foundation.sdsu.edu
Twitter | Facebook | Instagram | LinkedIn
Service - Collaboration - Innovation - Diversity - Integrity

Your feedback counts! Did I help you today? Please take this brief service survey. If you have any questions, please feel free to reach out to the Service Desk Team.

---------- Forwarded message ---------
From: **Groner, Lexie** <lexie_groner@unc.edu>
Date: Fri, Mar 21, 2025 at 1:20 PM
Subject: [EXT] SGM SOL Grant Termination Notice
To: Linda Gallo <lgallo@sdsu.edu>
Cc: dfields2@sdsu.edu <dfields2@sdsu.edu>, Ana Talavera <atalavera@sdsu.edu>, Perreira, Krista <krista_perreira@med.unc.edu>

Hello,

We wanted to let you know that we received a termination letter for the grant R01-HL149778 "Cardiovascular Health of Sexual and Gender Minorities in the Hispanic Community Health Study/Study of Latinos (SGM HCHS/SOL)" with a stop date of 3/20/2025. **We will not be able to accept any additional charges for work performed.** Krista will be in touch to discuss when she has more information.

Thank you and please let us know if you have any questions.

Lexie

Lexie Groner
Research Administrator
Carolina Population Center
The University of North Carolina at Chapel Hill
lexie_groner@unc.edu
She/her



03/20/2025

R. David Paul
UNIV OF NORTH CAROLINA CHAPEL HILL
resadminosr@unc.edu

Dear R. David Paul:

Effective with the date of this letter, funding for Project Number 5R01HL149778-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 03/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S
Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 16:46:43 -04'00'

Michelle G. Bulls, on behalf of Anthony Agresti, Chief Grants Management Officer, National Heart, Lung, and Blood Institute
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 22

Raman Paul

From: Susan Pelton
Sent: Friday, March 21, 2025 10:01 AM
To: Raman Paul; Rain Lee; Jocelyn B Tolentino; Kari Wong; Jenny Chau
Cc: Joshua David Calder
Subject: FW: Grant Termination Notification

From: Joshua David Calder <jdcalder@sfsu.edu>
Sent: Friday, March 21, 2025 9:47 AM
To: Susan Pelton <spelton@sfsu.edu>
Subject: Fw: Grant Termination Notification

It must be Friday ... Here is a termination letter for Emma's U grant effective today ... Not sure if anybody else got it?

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:31 AM
To: Joshua David Calder <jdcalder@sfsu.edu>
Subject: Grant Termination Notification

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

Joshua Calder
San Francisco State University
jdcalder@sfsu.edu

Dear Joshua Calder:

Effective with the date of this letter, funding for Project Number 5U01MH136574-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency

or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 23



From: Danielian, Anna <anna.danielian@csun.edu>
Date: Tuesday, March 25, 2025 at 8:39 AM
To: Manzueta, Charlene Rosenda <charlene.manzueta@csun.edu>
Subject: FW: Notice of Termination: Subaward 253405666 with UW-Milwaukee

From: Jeremy T Miner <minerj@uwm.edu>
Date: Monday, March 24, 2025 at 7:25 PM
To: Capous-Desyllas, Moshoula <moshoula@csun.edu>, Danielian, Anna <anna.danielian@csun.edu>, Quevedo, Sabrina Jessica <sabrina.quevedo@csun.edu>, RSP Awards <awards@csun.edu>
Cc: Priya Nambisan <nambisap@uwm.edu>, UWM Office of Sponsored Programs - Sub-Awards <or-osp-subawards@uwm.edu>, Carla Durand <durandc@uwm.edu>, Kristian M OConnor <krisocon@uwm.edu>, Monica L Wendel <wendel@uwm.edu>, Lance Weinhardt <weinhard@uwm.edu>, Michael D Laiosa <laiosa@uwm.edu>, Jennifer B Herzog <herzogj@uwm.edu>
Subject: Notice of Termination: Subaward 253405666 with UW-Milwaukee

Dr. Desyllas and colleagues,

The University of Wisconsin-Milwaukee has received official notice of termination for grant 1R01MH135498-01A1, titled “Using digital photovoice to explore the relationships between social media content and suicidality among transgender adolescents.” As a result, we are

unable to proceed with the subaward agreement (253405666). The effective date of the termination was March 21, 2025.

We appreciate your collaboration with UW-Milwaukee.

Jeremy

****

Jeremy T. Miner
Associate Director of Pre-Award
Office of Sponsored Programs
University of Wisconsin-Milwaukee
414-251-9255
minerj@uwm.edu

****

Outlook

Fw: Grant Termination Notification

From UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Date Mon 3/24/2025 7:47 AM
To Office of Research Support <or-support@uwm.edu>

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 11:35 AM
To: UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Subject: Grant Termination Notification



3/21/2025

Jeremy Miner
University Of Wisconsin Milwaukee
GRANT-NOTICE@UWM.EDU

Dear Jeremy Miner:

Effective with the date of this letter, funding for Project Number 1R01MH135498-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/5/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]„ According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of

many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 24

[redacted]

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date: Monday, March 24, 2025 at 12:53 PM
To: Manzueta, Charlene Rosenda <charlene.manzueta@csun.edu>
Subject: Grant Termination Notification

National Institutes of Health
Office of Extramural Research

3/24/2025

Ms. Manzueta, Charlene Rosenda
California State University Northridge
charlene.manzueta@csun.edu

Dear Ms. Manzueta, Charlene Rosenda:

Effective with the date of this letter, funding for Project Number 5U01MD017434-02 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 12/1/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

Wednesday, March 26, 2025 at 13:12:31 Pacific Daylight Time

Subject: FW: Grant Termination Notification - Subaward A22-0039-S002
Date: Tuesday, March 25, 2025 at 7:19:23 PM Pacific Daylight Time
From: Manzueta, Charlene Rosenda
To: kimmy@sipacares.org
CC: Bautista Lopez, Erika, Galvez, Joseph A, Kwan, Patchareeya P, Rillorta, Marie, Slavik, Grace Pauline
Attachments: image001.jpg, image002.png, image003.png

Dear Executive Director Kimmy Maniquis:

We regret to inform you that California State University, Northridge, has received an official termination notice for grant 5U01MD017434-02. Below is the email notice regarding this matter.

As a result of this notice, we are unable to proceed with the subaward agreement A22-0039-S002. The effective date of termination is March 24, 2025. We will inform you of any updates as we seek legal guidance regarding this notice.

Due to this notice, please halt any expenditures beyond March 24, 2025, as they will be deemed unallowable. Additionally, we kindly request that your organization submit any unpaid invoices promptly so we can process them as soon as possible.

We appreciate your partnership with Dr. Patty Kwan and our institution. Please forward this notice to the appropriate contacts at your organization. If you have any questions, do not hesitate to reach out.

Thank you for your time and attention,

Charlene

Charlene Rosenda Manzueta, EdD, MA, CRA
Managing Director, Research and Sponsored Programs, AOR | IO
California State University, Northridge
18111 Nordhoff Street (Valera Hall 275), Northridge, CA 91330-8232
(Direct Tel) 818.677.5008 | (Office Tel) 818.677.2901 | (Fax) 818.677.4691
| Charlene.Manzueta@csun.edu

CSUN | CALIFORNIA STATE UNIVERSITY NORTHRIDGE

--

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date: Monday, March 24, 2025 at 12:53 PM
To: Manzueta, Charlene Rosenda <charlene.manzueta@csun.edu>
Subject: Grant Termination Notification

NIH National Institutes of Health
Office of Extramural Research

3/24/2025

Ms. Manzueta, Charlene Rosenda
California State University Northridge
charlene.manzueta@csun.edu

Dear Ms. Manzueta, Charlene Rosenda:

Effective with the date of this letter, funding for Project Number 5U01MD017434-02 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 12/1/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.****[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the

issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Wednesday, March 26, 2025 at 13:10:46 Pacific Daylight Time

Subject: FW: Grant Termination Notification - Subaward A22-0039-S004
Date: Tuesday, March 25, 2025 at 7:34:42 PM Pacific Daylight Time
From: Manzueta, Charlene Rosenda
To: chancee@thaicdc.org
CC: Bautista Lopez, Erika, Galvez, Joseph A, Kwan, Patchareeya P, Slavik, Grace Pauline, Rillorta, Marie
Attachments: image001.jpg, image002.png, image003.png

Dear Executive Director Chancee Martorell:

We regret to inform you that California State University, Northridge, has received an official termination notice for grant 5U01MD017434-02. Below is the email notice regarding this matter.

As a result of this notice, we are unable to proceed with the subaward agreement A22-0039-S004. The effective date of termination is March 24, 2025. We will inform you of any updates as we seek legal guidance regarding this notice.

Due to this notice, please halt any expenditures beyond March 24, 2025, as they will be deemed unallowable. Additionally, we kindly request that your organization submit any unpaid invoices promptly so we can process them as soon as possible.

We appreciate your partnership with Dr. Patty Kwan and our institution. Please forward this notice to the appropriate contacts at your organization. If you have any questions, do not hesitate to reach out.

Thank you for your time and attention,

Charlene

Charlene Rosenda Manzueta, EdD, MA, CRA
Managing Director, Research and Sponsored Programs, AOR | IO
California State University, Northridge
18111 Nordhoff Street (Valera Hall 275), Northridge, CA 91330-8232
(Direct Tel) 818.677.5008 | (Office Tel) 818.677.2901 | (Fax) 818.677.4691
| Charlene.Manzueta@csun.edu

CSUN | CALIFORNIA STATE UNIVERSITY NORTHRIDGE

--

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date: Monday, March 24, 2025 at 12:53 PM
To: Manzueta, Charlene Rosenda <charlene.manzueta@csun.edu>
Subject: Grant Termination Notification

NIH National Institutes of Health
Office of Extramural Research

3/24/2025

Ms. Manzueta, Charlene Rosenda
California State University Northridge
charlene.manzueta@csun.edu

Dear Ms. Manzueta, Charlene Rosenda:

Effective with the date of this letter, funding for Project Number 5U01MD017434-02 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 12/1/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.****[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the

issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 25

From: Jennifer Sneed on behalf of SDSURF Awards
To: SDSURF Federal Impact Responses
Subject: Fwd: [EXT] Important Notice Regarding Subawards under NIH Prime Award UM2HD111102
Date: Wednesday, March 26, 2025 7:04:48 AM
Attachments: Outlook-A close-up.jfif
5UM2HD111102-03-Noa.pdf

Good morning. I do not think this was forwarded yesterday. This is for Dr. Horvath's subawards, funds- 5B104C and 5B547B. We did receive an update about this from Dr. Horvath yesterday and have already started our internal processes.

Yesterday we received the termination notices, this is now the matching NOA. We have not received the subaward end date amendments/termination notice directly yet.

Thank you, Jenny

---------- Forwarded message ---------
From: **Aras Aziz** <asaziz@fsu.edu>
Date: Tue, Mar 25, 2025 at 1:55 PM
Subject: [EXT] Important Notice Regarding Subawards under NIH Prime Award UM2HD111102
To: Angie Eaton <aeaton2@fsu.edu>, Lisa Hightow-Weidman <lhightowweidman@fsu.edu>
Cc: Rose Driber <rdriber@fsu.edu>

Florida State University received the attached termination from the NIH for prime award UM2HD111102. Our records show that your institution has received a subaward from FSU under this prime award. The effective date of the termination is 3/21/2025. While we determine our next steps, we ask for your cooperation and assistance. Additional information will be forthcoming as soon as possible.

A close-up of a logo

Aras Aziz, MA, CRA
Subcontract Officer III
Florida State University
(850) 644-8654
(850) 491-5799
asaziz@fsu.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:30:10 PM
To: SRA Pre-Award General Mailbox <SRA-PRE@fsu.edu>
Subject: Grant Termination Notification



3/21/2025

Stacey Patterson
Florida State University
SRA-PRE@fsu.edu

Dear Stacey Patterson:

Effective with the date of this letter, funding for Project Number 5UM2HD111102-03 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 12/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 26

From: Jennifer Sneed on behalf of SDSURF Awards
To: SDSURF Federal Impact Responses
Subject: Fwd: [EXT] Important Notice Regarding Subawards under NIH Prime Award UM2HD111102
Date: Wednesday, March 26, 2025 7:04:48 AM
Attachments: Outlook-A close-up.jfif
5UM2HD111102-03-Noa.pdf

Good morning. I do not think this was forwarded yesterday. This is for Dr. Horvath's subawards, funds- 5B104C and 5B547B. We did receive an update about this from Dr. Horvath yesterday and have already started our internal processes.

Yesterday we received the termination notices, this is now the matching NOA. We have not received the subaward end date amendments/termination notice directly yet.

Thank you, Jenny

---------- Forwarded message ---------
From: **Aras Aziz** <asaziz@fsu.edu>
Date: Tue, Mar 25, 2025 at 1:55 PM
Subject: [EXT] Important Notice Regarding Subawards under NIH Prime Award UM2HD111102
To: Angie Eaton <aeaton2@fsu.edu>, Lisa Hightow-Weidman <lhightowweidman@fsu.edu>
Cc: Rose Driber <rdriber@fsu.edu>

Florida State University received the attached termination from the NIH for prime award UM2HD111102. Our records show that your institution has received a subaward from FSU under this prime award. The effective date of the termination is 3/21/2025. While we determine our next steps, we ask for your cooperation and assistance. Additional information will be forthcoming as soon as possible.



Aras Aziz, MA, CRA
Subcontract Officer III
Florida State University
(850) 644-8654
(850) 491-5799
asaziz@fsu.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:30:10 PM
To: SRA Pre-Award General Mailbox <SRA-PRE@fsu.edu>
Subject: Grant Termination Notification



3/21/2025

Stacey Patterson
Florida State University
SRA-PRE@fsu.edu

Dear Stacey Patterson:

Effective with the date of this letter, funding for Project Number 5UM2HD111102-03 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 12/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 27

SDSU

Jennifer Sneed <jsneed@sdsu.edu>

Fwd: Immediate Action Required - Termination Letter 1R61 MH133710-01A1

1 message

Aaron J. Blashill <ajblashill@sdsu.edu> Fri, Mar 21, 2025 at 10:57 AM
To: sdsurf_federalimpacts@sdsu.edu, Michele Goetz <mgoetz@sdsu.edu>, Vanessa Malcarne <VMALCARNE@sdsu.edu>

Hi Michele--our sub award from Auburn, the R61 eating disorder treatment student was just cancelled--please see below and attached. I'm currently in Dallas, as my son was just born here a couple of days ago--I would like to speak to you today if possible, given the impact on Arjan, our fulltime coordinator (Nathaniel Holmes) and one of my PhD students (Em Chakkour) who are all funded on this grant. My cell is 857-998-3398. I'm including Vanessa Malcarne on this message as JDP director.

Thank you,
Aaron

Aaron J. Blashill, Ph.D.
Professor, Department of Psychology
Director, BISH Lab
San Diego State University
SDSU/UCSD Joint Doctoral Program in Clinical Psychology
6363 Alvarado Court, Suite 101
San Diego, CA 92120
(T) 619-594-2245
https://bishlab.sdsu.edu
Pronouns: He/Him/His (What's this?)

---------- Forwarded message ---------
From: **Tiffany Brown** <tiffanybrown@auburn.edu>
Date: Fri, Mar 21, 2025 at 12:49 PM
Subject: Fwd: Immediate Action Required - Termination Letter 1R61 MH133710-01A1
To: Aaron J. Blashill <ajblashill@sdsu.edu>

Sent from my iPhone

Begin forwarded message:

From: Sponsor Programs <OSPADMN@auburn.edu>
Date: March 21, 2025 at 9:21:21 AM CDT
To: Tiffany Brown <tiffanybrown@auburn.edu>
Cc: Cynthia Bowling <bowlicj@auburn.edu>, Savannah Mehren <shm0015@auburn.edu>, Konnie Pace <kdp0038@auburn.edu>, Ginger Phillabaum <phillgp@auburn.edu>, Gina Bailey <bailerh@auburn.edu>, Sheilah Wiley <ssw0044@auburn.edu>
Subject: FW: Immediate Action Required - Termination Letter 1R61 MH133710-01A1

Good morning Dr. Brown,

As I believe you may have already been notified, the attached letter provides the termination of Award 1R16 MH133710-01A1 (AU Fund 201432) from NIH. The termination date is as of March 21, 2025. Please ensure all expenditures are ceased at

this point and that all charges prior to the termination date are in place for invoicing purposes. I have also copied the subaward team so that a modification can be issued to both San Diego State and Yale University.

While not unexpected, I am very sorry to have to share this news with you. If I can be of any assistance, please do not hesitate to reach out.

Warm regards,
Tony

From: Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov> **On Behalf Of** Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 6:19 AM
To: Sponsor Programs <OSPADMN@auburn.edu>
Cc: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>; Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov>; Jarosik, Theresa (NIH/NIMH) [E] <theresa.jarosik@nih.gov>
Subject: [EXT] Immediate Action Required - Termination Letter 1R61 MH133710-01A1

CAUTION: Email Originated Outside of Auburn.

Please see attached.

TerminationLetter_1R61MH133710-01A1_03212025.pdf
256K



March 21, 2025

James Weyhenmeyer
Auburn University
ospadmn@auburn.edu

Dear James Weyhenmeyer:

Effective with the date of this letter, funding for Project Number 1R61 MH133710-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 1, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 28

University of Colorado
Denver | Anschutz Medical Campus

Office of Grants and Contracts
Research Administration
13001 East 17th Place
Aurora, CO 80045

San Diego State University Research Foundation
Attn: Sandra M. Nordahl | sdsurfawards@sdsu.edu

Re: Termination of Subaward number: FY24.1259.002

Project: *Proud to Quit (P2Q): A Person-centered mobile technology intervention for smoking cessation among transgender adults*

Prime #: 5R34DA058191-02

On March 21, 2025, National Institutes of Health issued the attached Notice to Terminate this project in full as of March 21, 2025 ("Termination Date"). Please cease all work on this project immediately. No new costs can be incurred on the subaward on or after the Termination Date.

Please communicate the above instructions to any lower-tier subrecipients you may have on this award.

Thank you,

Liz Causey

Liz Causey
Assistant Director of Contracts
Office of Grants & Contracts

University of Colorado
Denver | Anschutz Medical Campus

Office of Grants and Contracts
Research Administration
13001 East 17th Place
Aurora, CO 80045



3/21/2025
Alex Franz
University Of Colorado Denver
ALEX.FRANZ@CUANSCHUTZ.EDU

Dear Alex Franz:
Effective with the date of this letter, funding for Project Number 5R34DA058191-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]
The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]
The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."
This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.
Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.
Costs resulting from financial obligations incurred after termination are not allowable.[7]
Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]
Administrative Appeal

University of Colorado
Denver | Anschutz Medical Campus

Office of Grants and Contracts
Research Administration
13001 East 17th Place
Aurora, CO 80045

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11] The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Pamela Fleming, Chief Grants Management Officer, NIDA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

EXHIBIT 29

UNIVERSITY OF CALIFORNIA, SAN DIEGO UCSD

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

SPONSORED PROJECTS OFFICE
University of California, San Diego
9500 Gilman Drive #0934
La Jolla, CA 92093-0934

March 20, 2025

To: San Diego State University Research Foundation

Subject: Termination of Subaward No: 703792 (“Subaward”)

Dear San Diego State University Research Foundation colleagues,

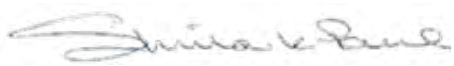
We regret to inform you that the Regents of the University of California, San Diego (“UCSD”) received an official notification of termination from NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH) (“Agency”) for the NEXUS: A novel social network approach to study the effects of intersectional stigma on HIV prevention among Latino MSM *(5R01MH123282)*, effective 3/20/2025.

Accordingly, you are hereby notified that the Subaward is terminated. All work must stop immediately, including termination of all subcontracts and activities. Please follow close-out procedures specified in the Subaward, including Agency requirements. UCSD will only be able to reimburse Subrecipient for costs reimbursed by Agency.

Please confirm receipt of this message on behalf of your organization.

It has been a privilege collaborating with you, and we look forward to the opportunity to work together again in the future.

Sincerely



Sheila K. Paul
Manager- Outgoing Subaward Team



03/20/2025

Nina Quach
UNIVERSITY OF CALIFORNIA, SAN DIEGO
nihawards@ucsd.edu

Dear Nina Quach:

Effective with the date of this letter, funding for Project Number 5R01MH123282-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 05/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 30



March 12, 2025

Rick Gulizia
San Diego State University
sdsurfawards@sdsu.edu

Dear Rick Gulizia:

Funding for Project Number 5R01MH133821-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on May 1, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *SAspending.gov.*

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 23:37:45 -04'00'

Michelle G. Bulls, on behalf Terri Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 31

SDSU

Jennifer Sneed <jsneed@sdsu.edu>

Fwd: FW: Subcontract Amendment 00129241/00079361 - Terminated

1 message

Jennifer Sneed <jsneed@sdsu.edu> Sat, Mar 29, 2025 at 12:59 PM
To: Jennifer Sneed <jsneed@sdsu.edu>

---------- Forwarded message ---------
From: **Delwyn Catley** <dcatley@sdsu.edu>
Date: Fri, Mar 28, 2025 at 2:25 PM
Subject: FW: Subcontract Amendment 00129241/00079361 - Terminated
To: Annie Moore <amoore3@sdsu.edu>, jsneed@sdsu.edu <jsneed@sdsu.edu>

Well here's the first one of ours to get the chop. It wasn't on my radar b/c I thought we'd spent it out by the grant end date which I believe was back in Dec. But online it looks like there is $394 left. If I'm remembering right this was the amount left when the grant ended but we got a no-cost extension so I think we should have spent this out subsequently. In any event, I have been continually working on this project up until now so I see no reason why we can't bill for effort prior to March 21 to zero this out.

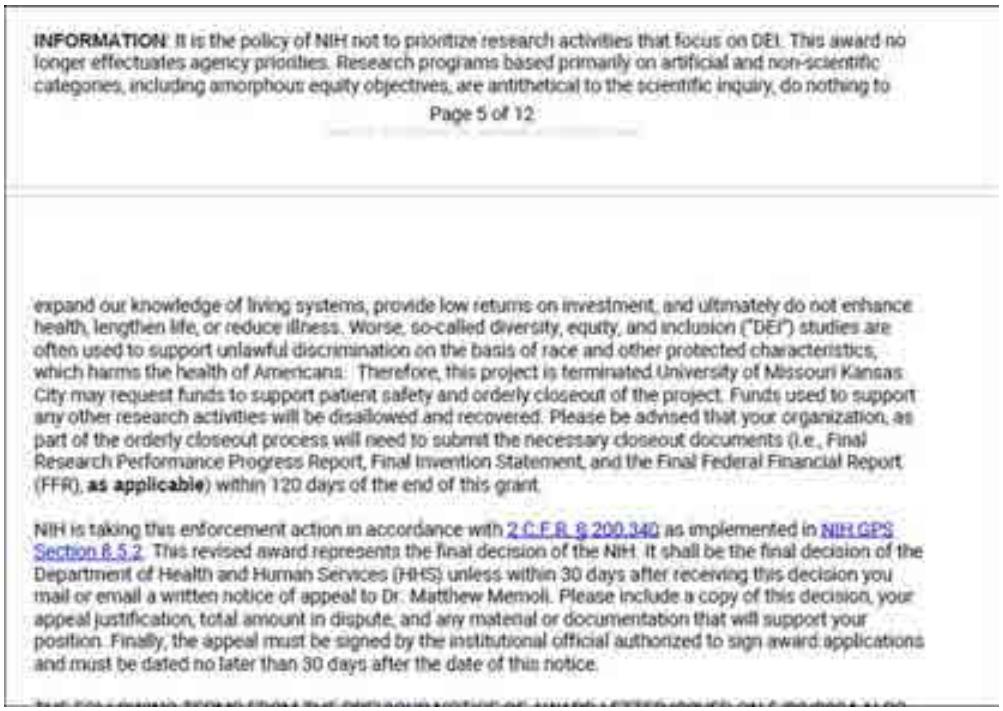
Delwyn

From: Health Sciences District Research Administration <hsdresearch@umkc.edu>
Date: Friday, March 28, 2025 at 11:51 AM
To: Annie Moore <amoore3@sdsu.edu>, Delwyn Catley <dcatley@sdsu.edu>, Sarah Harper <sharper@sdsu.edu>
Cc: Berkley Patton, Jannette <berkleypattonj@umkc.edu>, Hecker, Mark <heckerm@umkc.edu>
Subject: [EXT] Subcontract Amendment 00129241/00079361 - Terminated

Hello,

We are saddened to inform you that NIH Grant "Faithful Response II: COVID-19 Rapid Test-to-Treat with Kansas City Missouri Health African American Churches" has been terminated effective March 21st 2025. Therefore, our subcontract with (Principal Investigator Dr. Delwyn Catley) also needs to be terminated. UMKC Principal investigator, Dr. Berkley-Patton, plans to appeal the NIH decision, however, we wanted to let you know and to please submit any invoices for expenses prior to 3/21/2025, for payment.

Reason for termination stated in the updated NIH award letter dated 3/23/2025:



INFORMATION: It is the policy of NIH not to prioritize research activities that focus on DEI. This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to

Page 5 of 12

expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, this project is terminated.University of Missouri Kansas City may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Thank you,

Clare Carson

Grant Specialist

Cmkmv7@umkc.edu

University Health and the UMKC School of Medicine

Research Administration

2411 Holmes Street

Kansas City, MO 64108

☎ P: 816-235-5366

Office = UMKC School of Medicine, 4th floor (M4-309) Blue-unit

UMKC School of Medicine

SDSU

NIH_NOA_1U01MD018310-01_3.25.2025.pdf
320K

EXHIBIT 32

Raman Paul

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Wednesday, March 26, 2025 11:25 AM
To: Susan Pelton
Subject: Grant Termination Notification





3/26/2025

Susan Pelton
San Francisco State University
spelton@sfsu.edu

Dear Susan Pelton:

Effective with the date of this letter, funding for Project Number 5U01ES036366-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jenny Greer, Chief Grants Management Officer, NIEHS
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Raman Paul

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Wednesday, March 26, 2025 11:25 AM
To: Susan Pelton
Subject: Grant Termination Notification





3/26/2025

Susan Pelton
San Francisco State University
spelton@sfsu.edu

Dear Susan Pelton:

Effective with the date of this letter, funding for Project Number 3U01ES036366-03S1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jenny Greer, Chief Grants Management Officer, NIEHS
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Raman Paul

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Wednesday, March 26, 2025 11:25 AM
To: Susan Pelton
Subject: Grant Termination Notification





3/26/2025

Susan Pelton
San Francisco State University
spelton@sfsu.edu

Dear Susan Pelton:

Effective with the date of this letter, funding for Project Number 3U01ES036366-03S2 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 11/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jenny Greer, Chief Grants Management Officer, NIEHS
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 33

orsp@sfsu edu

From: Columbia University – SPA <spa@cumc.columbia.edu>
Sent: Saturday, March 22, 2025 7:16 AM
To: orsp@sfsu edu
Cc: Columbia University – SPA; grantreview@columbia.edu; Hughes, Tonda L.
Subject: Important Information regarding your Subaward with Columbia University

Re: Prime award No. 5R01AA027252-05
Subaward No. 1(GG014711-01)

Dear Partner:

The University received notice from the US Government, that it has terminated the above-referenced award in full, effectively immediately. Given the complexity of subaward management, we will be managing subawardees on a case-by-case approach, and will be in touch with you for further discussion and information.

In the meantime, you must immediately limit expenditures on the award only to those necessary to achieve a minimum level of research continuity. New equipment purchases and travel are prohibited. Columbia does not anticipate reimbursing expenditures that exceed a historical run-rate on the award (with the run-rate excluding travel, equipment and significant one-time purchases). If you anticipate your personnel expenses in the thirty-day period ending March 31, 2025 will exceed 5% of the total annual personnel budget, and you are concerned about research continuity at this level of expenditure, you must request advance approval for expenditure. You may submit any request for approval to the Columbia PI, who will escalate it within the University for appropriate approval.

Please confirm receipt of this communication and that you have understood and actioned the directive on the above-referenced award.

Thank you for your understanding and prompt attention to this matter.

Sincerely,

William Berger
Assistant Vice President
Sponsored Projects Administration
Columbia University

EXHIBIT 34

---------- Forwarded message ---------
From: **Research Foundation Office Sponsored Projects Mailbox** <research-foundation-osp@sjsu.edu>
Date: Mon, Mar 3, 2025 at 9:43 AM
Subject: Fwd: Termination of Subaward No. KK2321
To: Jessica Trask <jessica.trask@sjsu.edu>, VP of Research and Innovation Mailbox <vp.researchandinnovation@sjsu.edu>

Hi Jessica,
Please see below with the PTE. NIH is canceling an award. Laurie Drabble is the PI. Let me know what information you need.
Thank you,
Deb

---------- Forwarded message ---------
From: **Daniela Gallardo** <gallardo@research.ucsb.edu>
Date: Fri, Feb 28, 2025 at 4:46 PM
Subject: Termination of Subaward No. KK2321
To: <research-foundation-osp@sjsu.edu>
Cc: Bethany Guerrero <baguerrero@ucsb.edu>, Ector Flores-Garcia <efloresgarcia@ucsb.edu>, GGSE Contracts & Grants team <CG.team@education.ucsb.edu>

Hello,

NIH has decided to terminate the award titled, "Health Effects of Intersectional Stigma among Sexual minority Women" on February 28, 2025, effective immediately. With that said all activities must be ceased and we must terminate all subawards, including subaward no. KK2321, under this project (R21AA029513). I have attached a copy of the notification for reference.

We will provide you with an official notification in the coming days.

If you have any questions or would like to discuss further, please let me know.

best,
Daniela

Daniela Gallardo

Sr. Sponsored Projects Officer/Subaward Officer

Office of Research
Office: (805) 893-7027
Email: gallardo@research.ucsb.edu

Email Offline Day: Thursday
Upcoming out of office:
Upcoming office closure: March 21 (Holidays)

National Institutes of Health

Public Health Service
National Institutes of Health
National Institute on
Alcohol
Abuse and Alcoholism
6700B Rockledge Drive
Bethesda, MD 20892-6902

February 28, 2025

Elizabeth Carrillo
Sponsored Projects Analyst
The Regents of the University of California, Santa Barbara
3227 Cheadle Hall, 3rd Floor
Santa Barbara, CA 931062050

Dear Elizabeth Carrillo,

Funding for Project Number 5 R21 AA029513-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/18/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5 R21 AA029513-02 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *SAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Matthew J. Memoli, MD, MS, Acting Director, National Institutes of Health no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Matthew J. Memoli, MD, MS, Acting Director, National Institutes of Health may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Judy S. Fox

Judy S. Fox -S Digitally signed by Judy S. Fox -S
Date: 2025.02.28 18:13:05 -05'00'

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT 35

Friday, March 28, 2025 at 09:04:37 Pacific Daylight Time

Subject: FW: Information regarding URISE award
Date: Thursday, March 27, 2025 at 11:06:25 Pacific Daylight Time
From: Imelda Hammes
To: Gillian Fischer, Chi Nguyen, Dakota Hughes

FYI

Imelda Hammes
Post Award Analyst
Office of Sponsored Research and Programs
(T) 310-243-2855
ihammes@csudh.edu

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Sent: Thursday, March 27, 2025 11:00 AM
To: Imelda Hammes <ihammes@csudh.edu>
Subject: Information regarding URISE award

RE: T34 GM140930-03

Contact PI: MCCAULEY, ERIN PATRICIA

Organizational Representative IMELDA HAMMES,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 36

From: Vas Narayanaswami
To: Bessie Strategos; Crystal Trocadero; Jason Schwans
Cc: Cheyanne Ramon; Barbara Taylor; Curtis Bennett; Kelly Young; Yvette Castano
Subject: Fw: Information regarding URISE award
Date: Thursday, March 27, 2025 11:27:12 AM

Hello everyone,
Here is the response I received when I prompted the T34 program officer about the future of the URISE program....

I am going to go take a deep breath and process this information.

Vas

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Sent: Thursday, March 27, 2025 11:03 AM
To: Vas Narayanaswami <vas.narayanaswami@csulb.edu>
Subject: Information regarding URISE award

You don't often get email from rosenzwj@nigms.nih.gov. Learn why this is important

CAUTION: This email was sent from an external source.

RE: T34 GM149378-02

Contact PI: NARAYANASWAMI, VASANTHY

Organizational Representative MS BESSIE STRATEGOS,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 37

Friday, March 28, 2025 at 15:57:53 Pacific Daylight Time

Subject: Information regarding URISE award
Date: Thursday, March 27, 2025 at 11:01:31 AM Pacific Daylight Time
From: Rosenzweig, Justin (NIH/NIGMS) [E]
To: Manzueta, Charlene Rosenda

RE: T34 GM136450-04

Contact PI: ZAVALA, MARIAELENA B

Organizational Representative MICHAEL EPPING,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 38

Outlook

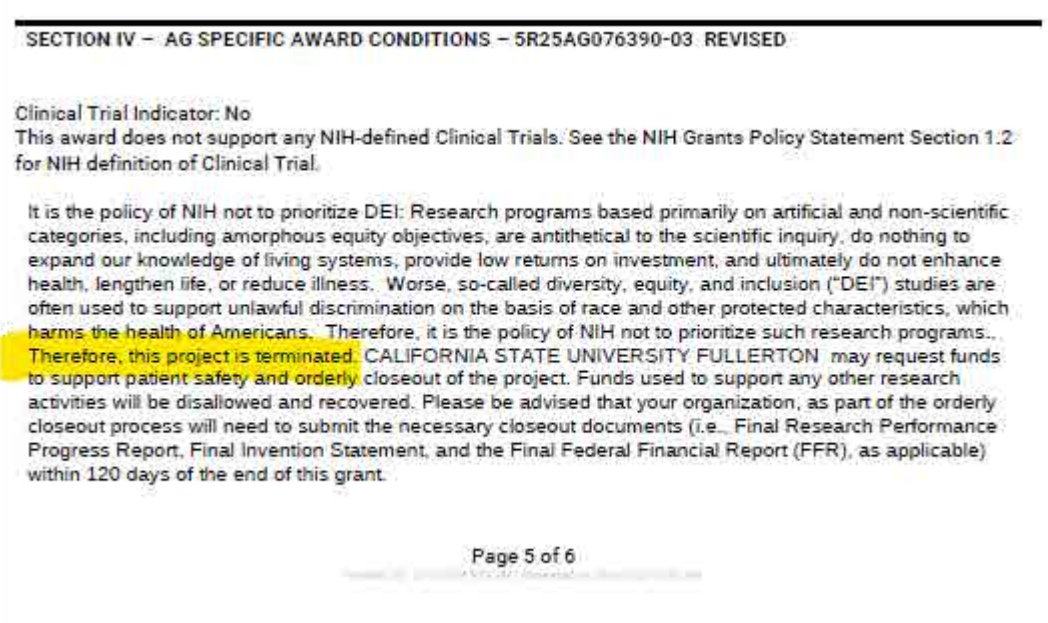
FW: [External] NoA: 5R25AG076390-03 PI: Jennifer Piazza

From Weber, Myrna <myweber@Fullerton.edu>
Date Mon 3/24/2025 2:55 PM
To Tiwari, Binod <btiwari@fullerton.edu>
Cc Tranilla, Tina <ttranilla@Fullerton.edu>; Riveron, Olga <oriveron@fullerton.edu>

1 attachment (235 KB)
5R25AG076390-03-Noa.pdf;

Hi Binod

We received a termination notice for Jennifer Piazza and Laura Zettel-Watson's R25.



SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R25AG076390-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

It is the policy of NIH not to prioritize DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.. Therefore, this project is terminated. CALIFORNIA STATE UNIVERSITY FULLERTON may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

Page 5 of 6

Myrna A. Weber, M.B.A. CRA
Sr Director, Sponsored Programs
1121 N. State College Blvd 2nd Floor ASC-213
Fullerton, CA 92831-3104
☎ 657-278-7679/Cell 714-864-8410
✉ myweber@fullerton.edu

CSUF | Office of Research and Sponsored Programs
ACADEMIC AFFAIRS

From: eraNotifications@mail.nih.gov <eraNotifications@mail.nih.gov>
Sent: Sunday, March 23, 2025 9:08 PM
To: Awards <awards@Fullerton.edu>
Subject: [External] NoA: 5R25AG076390-03 PI: Jennifer Piazza

Grant Number: 5R25AG076390-03
Principal Investigator: Piazza, Jennifer(Contact); Zettel-Watson, Laura
Project Title: A Multidimensional Aging Science Program: MSTEM Scholars Trained in Aging Research (MSTEM STAR)
Institution: CSU Fullerton Auxiliary Services Corporation
CFDA: 93.866
OC: 41032
PCC: 2BTRNDT
Award Issue Date: 03/24/2025
Grants Management Officer: Melvin, E.
Program Official: Torres, Delany
Grants Specialist: McGraw, Tracie

This is an automated notification - Please do not reply to this message.

EXHIBIT 39

Outlook

FW: Information regarding URISE award

From Cuajungco, Math <mcuajungco@fullerton.edu>
Date Thu 3/27/2025 11:13 AM
To Tiwari, Binod <btiwari@fullerton.edu>; Johnson, Marie <mariejohnson@Fullerton.edu>
Cc Le, Tran <trannle@Fullerton.edu>; Jimenez Ortiz, Veronica <vjimenezortiz@Fullerton.edu>

Good morning Binod and Marie,

I'm forwarding message I just got from NIH/NIGMS. It appears Year 3 continuation is pending and likely to be terminated (but still hoping things will turn around). Still very disappointing!

Math

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Date: Thursday, March 27, 2025 at 11:06 AM
To: Cuajungco, Math <mcuajungco@fullerton.edu>
Subject: [External] Information regarding URISE award

RE: T34 GM149493-02

Contact PI: CUAJUNGCO, MATH P

Organizational Representative MRS CATHERINE M ANDERS,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 40
[INTENTIONALLY OMITTED]

EXHIBIT 41

Raman Paul

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Sent: Thursday, March 27, 2025 11:00 AM
To: Raman Paul
Subject: Information regarding URISE award

RE: T34 GM145400-03

Contact PI: ESQUERRA, RAYMOND M

Organizational Representative RAMAN PAUL,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 42

---------- Forwarded message ---------
From: **Rosenzweig, Justin (NIH/NIGMS) [E]** <rosenzwj@nigms.nih.gov>
Date: Thu, Mar 27, 2025 at 11:06 AM
Subject: Information regarding URISE award
To: cleber.ouverney@sjsu.edu <cleber.ouverney@sjsu.edu>

RE: T34 GM149461-02
Contact PI: OUVERNEY, CLEBER COSTA
Organizational Representative DEBORAH MALONEY,
NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.
Sincerely,
Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 43

Outlook

RE: Information regarding URISE award

From Darya Veach <dveach@calpoly.edu>
Date Thu 3/27/2025 1:52 PM
To Dawn Brown Neill <dbneill@calpoly.edu>; Allie Bakaly Walter <abwalter@calpoly.edu>; Maral Kismetian <mkismeti@calpoly.edu>; Amy Velasco <aevelasc@calpoly.edu>
Cc Trish Brock <pbrock@calpoly.edu>; Alexis Renee Sexton <arsexton@calpoly.edu>

I'm including Trish and Alexis here as well. This if for Todd and Sarah Keadle's URISE project.

Summary of grant details:

Title: U-RISE at Cal Poly
Sponsor: NIH
Project: 45199
GDO: 22-289
Project period (as funded): 4/1/24-3/31/25 (originally awarded end date 3/31/2028)
Total awarded to date: $444,764.00 (total anticipated $1,334,291)
Expenditures as of 3/26/25: $352,914.84
Unspent balance: $91,849.16

Please let me know if you have specific questions. I'm sure additional information will be coming in the following days.

Thanks,
Darya

DARYA VEACH, M.S.
pronouns she/her
Director, Sponsored Programs Office
Division of Research
Cal Poly Partners
Cal Poly, San Luis Obispo, CA

Main: 805-756-1123
Direct: 805-756-5348
www.research.calpoly.edu
www.calpolypartners.org

From: Stephany Martin <smarti47@calpoly.edu>
Sent: Thursday, March 27, 2025 11:09 AM
To: Dawn Brown Neill <dbneill@calpoly.edu>; Allie Bakaly Walter <abwalter@calpoly.edu>; Darya Veach <dveach@calpoly.edu>; Maral Kismetian <mkismeti@calpoly.edu>; Amy Velasco <aevelasc@calpoly.edu>
Subject: FW: Information regarding URISE award
Importance: High

Hi, just received this. 45199/22-289

Thank you,

Stephany Martin
Contract & Grants Analyst

Division of Research
Sponsored Programs
San Luis Obispo, CA 93407
Phone: (805) 756-7322

https://research.calpoly.edu
https://calpolypartners.org/

From: Tyler Alvord <talvord@calpoly.edu>
Sent: Thursday, March 27, 2025 11:07 AM
To: Stephany Martin <smarti47@calpoly.edu>
Subject: Fw: Information regarding URISE award

Stephany -

Just making sure this got sent to you as well.

Thanks,

Tyler Alvord

Research Administration Officer II

California Polytechnic State University

San Luis Obispo, CA 93407-0001

Direct: 805-756-1449

https://grants.calpoly.edu/

Register here to set up your ORCID: https://orcid.org/signin

NSF requires investigators to use SciENcv to manage their biosketches and current and pending documents.

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Sent: Thursday, March 27, 2025 11:00 AM

To: Tyler Alvord <talvord@calpoly.edu>
Subject: Information regarding URISE award

RE: T34 GM149492-02

Contact PI: HAGOBIAN, TODD ALAN

Organizational Representative STEPHANY MARTIN,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

EXHIBIT 44

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nigms.nih.gov

April 2, 2025

Raman Paul
1600 Holloway Ave.
San Francisco, CA 94132

Dear Raman Paul:

Funding for Project Number 5T34GM145400-03 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on April 1, 2024 and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Matthew J. Memoli, M.D., M.S., Acting Director, NIH no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT 45

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200

http://www.nigms.nih.gov

April 2, 2025

California State University Fullerton
1121 N. State College Blvd.
Fullerton, CA 92831-3014

Olga Riveron:

Funding for Project Number 5T34GM149493-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on April 1, 2024 and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Matthew J. Memoli, M.D., M.S., Acting Director, NIH no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT 16

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF DR. MIGUEL GARCIA-DIAZ

I, Dr. Miguel Garcia-Diaz, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research, Scholarship, and Innovation at the University of Delaware. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am a Professor of Chemistry and Biochemistry and the Vice President for Research, Scholarship, and Innovation at the University of Delaware, a position I have held since May 1, 2024. In this capacity, I have oversight of all research and scholarship activities taking place at the University, including all research funded by the U.S. Department of Health and Human Services. Prior to holding this position, I was a Professor of Pharmacological Sciences at Stony Brook University's Renaissance School of Medicine, as well as interim Vice President for

Research for the University. I hold a PhD in Biochemistry from the Autonomous University of Madrid (Spain), conducted postdoctoral work at the National Institute of Environmental Health Sciences, and while at Stony Brook University led a research group focused on understanding a rare group of genetic diseases, work that was partially funded by the NIH.

4. The University of Delaware exists to cultivate learning, develop knowledge, and foster the free exchange of ideas. It is a major research university that serves as the flagship university for the State of Delaware. As such, it serves as a major economic engine for the Sate of Delaware, and, through its scholarship and research, addresses critical needs of the State and the Nation.

5. The University of Delaware has five campuses throughout the State of Delaware. While most of the University's educational and research programs are located on the Newark Campus, substantial research activity takes place on the Lewes campus, and key educational programs are offered in Wilmington, Dover, and Georgetown. The University has over twenty-four thousand students, including over four thousand graduate students. Its various research programs represent an annual investment of over $425M, including almost $200M in federal funding.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group) and given a priority score (based on scientific merit) that is within a range that would result in the

awarding of the grant funds. This is based on recent funding ranges of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade has had severe impact on the University of Delaware, primarily by disrupting critical research and halting vital projects. Additionally, it creates significant financial uncertainty, forcing the University to choose between dismantling existing, productive research groups or absorbing a substantial cost to provide bridge funding -without any clarity on when NIH grants will be awarded. Even when bridge funding is available, many top researchers are seeking positions elsewhere to avoid reliance on uncertain NIH funding.

8. Graduate students, who make up a large part of the NIH-funded workforce, are also affected. The NIH has long been a key source of funding for individual fellowships and training grants, which are essential for graduate education in NIH-relevant disciplines. Historically, stable federal funding has shaped the size of incoming graduate classes, but unexpected delays now strain the University's ability to support its current students, many of whom depend on stipends to pursue the years of advanced training required for a PhD. These funding gaps force the University to choose between absorbing significant financial strain or prematurely ending the careers of promising young scientists.

9. The uncertainty surrounding NIH funding has further led to reduced admission offers, jeopardizing the pipeline of the next generation of biomedical researchers. Faculty, whose work relies on decades-long institutional investments to sustain their world-class research programs, are also at risk. The traditional and longstanding partnership between research universities and the federal government—where institutions provide resources for faculty to lead groundbreaking, federally funded research—is now in jeopardy. Continued delays in NIH funding threaten this covenant, as some faculty consider alternative career opportunities. Such

losses would cause irreparable harm to the University and its contributions to science and technology.

Reliance on NIH Funding

10. In fiscal year 2024, the University of Delaware received funding through the National Institutes of Health ("NIH") to support 135 projects, totaling $66M.

11. The University of Delaware receives NIH grants across a variety of institutes encompassed within the NIH, including NIGMS, NCI, NIA, NIDA, NIDDK, NEI, NHLBI, NIAID, NIMH, NIAMS, NIDCD, NIBIB, NICHD, NIDCD, NIDCR, and NINR.

12. The work done by the University of Delaware on NIH funded projects provides education and training in Chemistry and Biochemistry, Biomedical Engineering, Chemical and Biomolecular Engineering, Computer and Software Engineering, Electrical and Computer Engineering, Mechanical Engineering, Agriculture, Biology, Mathematics, Psychology and Brain Science, and other programs.

13. The University of Delaware provides considerable employment opportunities in the Science, Technology, Engineering and Mathematics ("STEM") workforce which provides significant benefit to the Delaware economy.

Typical Timeline and Processes for NIH Grant Awards

14. The Research Office at the University of Delaware collaborates with researchers to submit and track grant applications and awards.

15. Based on my work as Vice President for Research, Scholarship, and Innovation and my career as a biomedical scientist, I have knowledge and an understanding of the NIH grant process.

16. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Current paylines typically range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

18. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming that the grant will be funded.

19. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

20. The budget process at the University of Delaware relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 12 months of submission.

21. Once a grant receives a score, the University of Delaware is able to consider whether to include the expected funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

22. Since late January 2025, the University of Delaware has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

23. The University of Delaware has not received formal notice of changes for many of these grants. For others, the University of Delaware has gotten only a notification that proposals are "paused" or "under review."

24. As of March 31, 2025, the University of Delaware has 77 proposals totaling $177M awaiting NIH study section review.

25. As of March 31, 2025, the University of Delaware has at least 13 proposals totaling $59.8M that received fundable scores, awaiting NIH advisory council and Notice of Award.

26. As of March 31, 2025, the University of Delaware has 102 proposals totaling $234.9M that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

27. Since March 22, 2025, the University of Delaware has had 3 NIH grants terminated where the University was a subawardee.

28. These terminations will result in the loss of $721,840 in research money to the University of Delaware.

29. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my time working at both the University of Delaware and Stony Brook University, I have not seen this language previously used to cancel grants.

30. To our knowledge, prior to receipt of the termination, Universities are not being given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities, or any notice of updated "agency priorities" with which its research must align.

31. The terminated awards supported research on HIV prevention and Alzheimer's Disease.

Comparisons Across Administrations

32. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

33. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

34. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

35. NIH Delays in proposal review and grant funding are creating financial uncertainty for the Univrsity of Delaware. The University's budget planning has historically relied on the predictability of NIH funding cycles and decisions, allowing the University to make informed decisions about resource allocation. However, the current uncertainty is disrupting this

process, making it increasingly difficult to maintain fiscal stability and develop accurate, reliable budgets both now and for the upcoming fiscal year. This uncertainty threatens not only individual research projects and jobs, but also the broader financial health of the institution.

36. To mitigate these disruptions, the University has been forced to implement emergency bridge funding for affected faculty, drawing from limited discretionary resources. As of March 31, 2025, the University of Delaware estimates it has allocated approximately $500,000 in bridge funding, funds that would have otherwise supported new research initiatives, faculty recruitment, and programmatic improvement. These unplanned expenditures are straining University resources and diverting funds from other critical institutional needs.

37. The uncertainty surrounding the grant funding has led to decreases in usage of shared research cores, which are essential for maintaining a robust research infrastructure. If researchers cannot rely on stable funding, they will be required to delay or cancel projects, reducing demand for these facilities. If this trend continues, it could lead to further financial losses and a decline in the University's research capacity.

Admissions, Training and Workforce Disruptions

38. The University of Delaware uses information regarding NIH grant applications and award rates to inform its graduate admissions process.

39. Due to uncertainty of incoming grant funding related to the delays in reviewing and awarding grants by NIH, the various PhD programs at the University of Delaware that rely on NIH funding for graduate student support have reduced admission offers for their incoming class of graduate students by up to 50%.

40. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions

so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

41. The University also anticipates that we will have international postdocs whose visa status will now be at risk due to pending NIH awards that were expected to renew this spring.

42. This instability is affecting the recruitment and retention of high-caliber quality research trainees. The inability to retain quality research trainees will have ongoing effects on the research capabilities of the University of Delaware, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

43. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

44. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

45. Our research administration staff have received informal feedback from NIH indicating that certain programs are being subject to internal agency review, further contributing to delays.

Irreparable Harm

46. The delays have disrupted ongoing research, as well as actively setting back the University of Delaware's ability to conduct critical research now and in the future. Funding gaps have already forced researchers to abandon promising studies, miss key deadlines, or lose highly trained personnel. Despite the University's efforts to provide interim funding, resources are

finite, and because of these delays the University is forced to make difficult decisions about which of these valuable programs to continue with these limited funds.

47. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding. This results in not only ethical and financial losses but also wasted scientific opportunity, as experiments cannot simply be restarted once interrupted.

48. In many cases, there is no way to recover the lost time, research continuity, or training value for graduate students and postdoctoral researchers once disrupted. Promising discoveries may be delayed indefinitely, and in some cases, entirely lost.

Conclusion

49. The breakdown in NIH processes is affecting University of Delaware operations and planning. Unexplained terminations and delays with no explanation or remedy are undermining confidence in the federal research funding system, destabilizing institutional operations, and eroding the morale of researchers. Equally troubling is the loss of qualified, highly trained research personnel, many of whom will seek more stable opportunities elsewhere, which risks permanently weakening the University's ability to contribute cutting-edge research to the scientific community. These harms are ongoing and, in many instances, irreparable.



Dr. Miguel Garcia-Diaz

Date: April 1, 2025

EXHIBIT 17

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., M v. ROBERT F. KENNEDY, JR., et al., M	No. 1:25-cv-_____

DECLARATION OF VASSILIS L. SYRMOS

I, Vassilis L. Syrmos, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Innovation of the University of Hawai i. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States Motion for Temporary Restraining Order.

Pr B r d

3. I am currently employed by the University of Hawai i (UH) as the Vice President for Research and Innovation. In addition to my current role, I have a Ph.D. in electrical engineering and over 30 years of academic experience. My office (the Office of the Vice President for Research and Innovation) tracks federal funding received by the University of Hawai i through grant awards, cooperative agreements, contracts and other agreements. My office facilitates the research enterprise for our researchers, faculty, students, staff and

administrators, funds system-wide initiatives, coordinates and executes our federal funding appropriations and programs, sets and monitors all policies for our research enterprise to comply with federal and state laws.

4. The University of Hawai i is the only public higher education institution in the State of Hawai i.

5. The University of Hawai i has 10 campuses, with a total enrollment of more than 50,000 students and more than 3,000 researchers. UH is one of the leading research universities in the nation, ranking in the top 20% of all public universities in research expenditures by the National Science Foundation Higher Education Research and Development (HERD) survey.

6. The University of Hawai‘i includes the John A. Burns School of Medicine (JABSOM), the University of Hawai‘i Cancer Center (a National Cancer Institute-designated center), the Daniel K. Inouye College of Pharmacy, the School of Nursing and Dental Hygiene, the Thompson School of Social Work and Public Health, and several more Health Sciences programs across all campuses. All these Schools, Colleges, and Centers conduct fundamental, translational, clinical, and community-based participatory research in health sciences and healthcare.

7. I am providing this declaration to explain the impacts of the National Institutes of Health (NIH) delay and/or cancellation of study sections. NIH s abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or study section (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds.

These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

8. The NIH meeting blockade severely impacts the University of Hawai i by causing tremendous budget uncertainty for non-competitive renewals awaiting the Notice of Award for the next project year (some of which start April 1, 2025) , and for those grants that received notice of being within the fundable range, based on their scientific merit and meeting Institute/Center priorities. JABSOM alone has 157 faculty and staff employees on current NIH funding, with more than half on projects awaiting Notice of Awards expected within the next two months for the next budget year.

R NIH F d

9. In the university s fiscal year 2024, the University of Hawai i received direct funding obligations through NIH to support 75 projects, totaling $65,449,960.

10. The University of Hawai i receives NIH grants across a variety of institutes encompassed within the NIH, including the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Human Genome Research Institute (NHGRI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of General Medical Sciences (NIGMS), National Institute of Neurological Disorders and Stroke (NINDS), National Institute on Aging (NIA), National Institute on Drug Abuse (NIDA), National Institute on Minority Health and Health Disparities (NIMHD), and the National Library of Medicine (NLM).

11. Through those NIH grants, the University of Hawai i funds 98 researchers, most of whom are part of JABSOM and the University of Hawai i Cancer Center, the state s only medical school and cancer center, respectively.

12. The work done by the University of Hawai i on NIH funded projects provides education, training, and research in Anatomy/Biochemistry/Physiology, Cancer Biology, Cancer Etiology/Epidemiology, Cell and Molecular Biology, Clinical Research, Data Science, Information and Computer Sciences, Library Sciences, Mechanical Engineering, Medicine, Nursing, Obstetrics/Gynecology, Pediatrics, Pharmacology, Public Health, Quantitative Health Sciences, Social and Behavioral Sciences, and Tropical Medicine.

13. The University of Hawai i provides considerable employment benefits to Hawai i s economy in the Science, Technology, Engineering, and Mathematics (STEM) workforce. In 2021, OVPRI commissioned the Economic Research Organization at the University of Hawai i (UHERO) to produce a report on the economic impact of the University of Hawai i on the state. Based on data from fiscal year 2020, the UHERO report provided a much-needed and clear snapshot of how UH research-related spending, whether direct, indirect, or induced, contributes to Hawai i s economy. By using similar trends, the increase in UH research-related expenditures to $607.3 million in FY 2024 resulted in: $935.9 million in total business sales, $301.6 million in total employee earnings, $52.4 million in total state tax revenue, and 6,919 jobs supported.

T T d Pr r NIH Gr A rd

14. The Office of Research Services at the University of Hawai i works with researchers to submit and track grant applications and awards.

15. Based on my work as the Vice President for Research and Innovation, I have an understanding of the NIH grant process based on my 12 years in the role and 32 years as a funded investigator.

16. NIH grant applications are typically submitted via NIH s online portal, often in response to a Notice of Funding Opportunity (NOFO) . From there, they are assigned to a study section where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a fundable score, there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors, as every institute or center is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal. Still, many others (special emphasis and non-CSR) will only result in an impact score without a percentile. Program officers have the latitude to recommend proposals with higher scores/percentiles to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

18. After the study section, the grant application is sent to an advisory council where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming if the grant will be funded.

19. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

20. The budget process at the University of Hawai i relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 4 to 5 months of submission.

21. Once a grant receives a score, schools and colleges within the University of Hawai i can consider whether to include the funding coming from that grant as part of their budget for the coming year.

D d Irr r Pr NIH Gr A

22. Since late January 2025, the University of Hawai i has seen unusual delays in processing NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

23. The University of Hawai i has not received formal notice of changes for many of these grants. For others, the University of Hawai i System has received only a notification that proposals are paused or under review.

24. As of March 30, 2025, the University of Hawai i has approximately 65 proposals awaiting NIH study section review.

25. As of March 30, 2025, the University of Hawai i has 31 proposals that received fundable scores, awaiting NIH advisory council and Notice of Award.

26. As of March 30, 2025, the University of Hawai i has 39 proposals that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

T r NIH Gr

27. Since March 21, 2025, the University of Hawai i has had two NIH grants terminated, not including subawards from other NIH-funded institutions.

28. These terminations will result in the loss of approximately $344,000 in research money to the University of Hawai i, assuming all funding for each grant is lost.

29. The University of Hawai i is also a site for the NIH RECOVER Initiative: A Multi-site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults, the grant for which New York University, as the prime awardee, received a termination notice on March 24, 2025. If the University of Hawai i s subaward is terminated, this would result in significant losses to UH into multiple hundreds of thousands of dollars. Additionally, based on notifications from Columbia University, two subawards from Columbia University have been terminated: (1) the long-term Diabetes Prevention Program Outcomes Study (DPPOS), which examines links between the highly common prediabetes and type 2 diabetes and Alzheimer s disease-related dementias, and studies on the impacts of diabetes prevention on cancer, heart disease, stroke, nerve damage, kidney disease, and eye disease and (2) the obesogenic origins of maternal and child metabolic health involving dolutegravir (ORCHID), which conducts specialized metabolic analysis for pregnant women living with HIV who are enrolled in this study.

30. The termination notices for the two grants terminated by NIH have provided very little to explain the termination, instead noting that the research no longer effectuates agency priorities. In my decades working at the University of Hawai i, I have not seen this language previously used to cancel grants.

31. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, the University of Hawai i had not been given notice of any opportunity to submit

any corrected grant materials to align with agency priorities. Nor was the University of Hawai i provided with any updated agency priorities with which its research must align.

32. The two terminated grants, which are based at JABSOM, are further described as follows:

(1) JABSOM s Minority Health Research Training (MHRT) T37 program, which has been continually funded for 12 years, engages undergraduate, post-baccalaureate, and graduate students from any discipline in national or international mentored research projects in tropical medicine, infectious diseases, community research, chronic disease, aging, substance abuse prevention and other high priority research topics. The T37 training programs are designed to help train the next generation of scientists from underrepresented backgrounds in science. The one-year training program includes mentoring and in-country training in locales throughout Asia, the Pacific, and Africa. MHRT has successfully trained students to pursue graduate and professional degrees with 66% of trainees pursuing graduate or professional studies, and one third (33%) who have earned doctoral level degrees, and are now working in the biomedical sciences practicing in their respective fields (e.g., academic faculty, physician, pharmacist). About 25% attend medical school.

(2) JABSOM s Evaluating HPV Vaccination Uptake Barriers and its Efficacy in PLWH is a diversity supplement to the parent RCMI Specialized Center grant, Ola HAWAII. Because cancer caused by the human papillomavirus (HPV) can often be prevented, this study examines how to increase proactive treatment in patients with pre-existing immune compromise (i.e., individuals living with an HIV infection). The early-stage investigator first developed a test that detects antibodies to the HPV types covered

in the 9-valent HPV vaccine, along with three other high-risk types that cause cancer. The study seeks to help at-risk patients accept treatment from their physicians. The study will also examine the effectiveness of such treatment in raising antibody levels against HIV and preventing clinical evidence of cancer in this at-risk population. If successful, the approaches used in this study can help inform treatment guidelines to prevent numerous cancers caused by this virus.

C r A r Ad r

33. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

34. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

35. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

I I O r

36. The University of Hawai i is starting the process to request new faculty positions and budgeting for Fiscal Year 2025-26. The uncertainty of whether a continuation award will be funded directly impacts the rest of that faculty member's department budget, the distribution of teaching workload among the entire department, and the ability to hire additional faculty, teaching assistants, and graduate assistants.

37. The MHRT grant termination has forced us to implement bridge funding for impacted students, drawing from limited discretionary resources. As of March 30, 2025, UH has implemented bridge funding of approximately $18,000 to cover the remainder of student payroll through the end of the academic year. This prevents using these funds for any other purpose.

38. For currently funded awards where start-up funding was committed, we will withhold future payments until there is more certainty on awarding of already-appropriated funds (i.e., non-competitive renewal) and may also pause offering start-up packages as the indirect cost recovery amounts are the source of bridge funding through employee termination, if no other funding sources are available. For faculty recruitments in process, the delays and uncertainties of NIH funding will limit our ability to offer start-up funding, which may result in those positions remaining unfilled.

E P F r S S r d Pr r

39. The loss of the NIH RECOVER initiative impacts the comprehensive, coordinated care patients suffering from long-term consequences receive. Patients with long COVID, who do not receive care in specialized multidisciplinary clinics, often experience delays in diagnosis and evidence-based treatments. Additionally, research results from the RECOVER initiative have led to an understanding of some mechanisms of illness, resulting in recently launched clinical trials to help with treatment or symptom reduction.

Ad Tr d W r r D r

40. The University of Hawai i uses that information regarding NIH grant applications and award rates to inform its admissions process at the graduate student level.

41. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions enabling them to train individuals in specific shortage areas (T32 grants) and support predoctoral dissertation research through F31 grants. Certain training mechanisms aiming to increase the science workforce to include many groups traditionally underrepresented in science and medicine, as defined by the National Science Foundation, the Americans with Disabilities Act of

1990, and based on financial and educational backgrounds, are also being targeted for termination (T34, MOSAIC K99/R00). These training mechanisms are highly competitive and reviewed for scientific rigor, in the same manner as all NIH proposals.

42. The University of Hawai i has international postdocs whose visa status is now at risk due to uncertainty of one of the K99/R00 awards and pending NIH awards that were expected to renew this spring.

43. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of the University of Hawai i, including limiting the individuals qualified to conduct certain research. The future of the highly competitive, high-value Pathways to Independence awards (K99/R00) is uncertain. JABSOM has two such awards one focused on cardiovascular biology and the other on colorectal cancer in Native Hawaiians.

C r A FY F d B O d

44. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

45. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

46. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to heightened scrutiny or internal concerns.

Irr r H r

47. The delays have disrupted ongoing research, and set back the University of Hawai i for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the interim funding measures being taken by UH to keep certain research going. UH has had to make plans about which of these valuable programs to continue with limited funds.

48. Some of these studies involve clinical trials for life-saving medications or procedures, and their closure would endanger the lives of patients. The NIH RECOVER initiative learns about the long-term effects of COVID. Thus far, all 110 Hawai i participants suffering from long-term health conditions have not recovered after two years. Research understanding some of the mechanisms has improved to the point where clinical trials are being launched to help with treatment or symptom reduction. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding.

49. Delays have also disrupted research with the education of our community partners, which is critical to ensure our research is highly relevant. The results will be utilized by the populations we work with and influence health policy. Grant terminations and delays greatly reduce student opportunities, which impact the next generation of scientists and physicians.

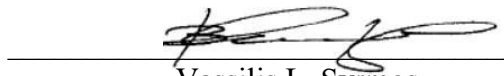
50. There is no way to recover the lost time, research continuity, or training value once disrupted.

C

51. The breakdown in NIH processes affects institutional operations, planning, and population health partnerships. Terminations and delays without explanation or remedy

undermine confidence in the system and research, in general. These harms are ongoing and, in many instances, irreparable.

Executed on March 31, 2025 at Honolulu, Hawai i.



Vassilis L. Syrmos

EXHIBIT 18

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF DR. DARRYLL J. PINES

I, Dr. Darryll J. Pines, hereby declare:

1. I am President of the University of Maryland, College Park ("UMCP"), a constituent institution of the University System of Maryland ("USM"), the State of Maryland's public system of higher education. This is a position I have held since 2020. As President, I have statutory responsibility and accountability to the USM's governing board, the Board of Regents, for developing the mission and successful conduct of UMCP and for the supervision of each of UMCP's schools and colleges. Prior to holding this position, I was Dean of the A. James Clark School of Engineering at UMCP, a position I held for 11 years.

2. As UMCP's President, I have personal knowledge of the matters set forth below or have knowledge of the matters based on my review of information and records gathered by my staff, including Dr. Gregory Ball, UMCP's Vice President for Research, other campus research administrators, and faculty members who serve as Principal Investigators on various NIH awards.

3. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Background

4. UMCP is the State of Maryland's flagship research university and is ranked by *Forbes* as #12 in the United States among public universities. UMCP enrolls over 40,000 students across twelve schools and colleges and an interdisciplinary Graduate School and offers over 300 degree programs. UMCP is a global leader in numerous areas of study, including mathematics, computer science, health, data science, climate science, and more. UMCP, along with its sister institution, the University of Maryland, Baltimore ("UMB"), engages in cross-cutting research that highlights the intersection of engineering, computer science, AI, and medicine. As one of the nation's leading research universities, UMCP is well positioned to advance and translate public health knowledge to improve health and well-being. Faculty and students are involved in a broad range of scientific endeavors and research centers whose focus spans from the cellular to the societal. UMCP's laboratories and research programs rely, in part, on NIH funding to make a difference in critical areas, such as understanding how respiratory viruses spread through air, climate change's impacts on health, physical activity's benefits to aging brains, innovative approaches to treating cancer, and advancing health equity, among others.

5. UMCP's research is supported by several different federal agencies. UMCP's extramural funding totaled over $703 million in State Fiscal Year (FY) 2024, including $68 million in funding awarded directly by the NIH and $9 million in funding awarded on a pass-through basis from the NIH.

6. I am providing this declaration to explain the impacts on UMCP of NIH's delays and/or cancellations of study sections and advisory council meetings and its terminations of grants.

7. NIH's abrupt cessation of NIH advisory council meetings in February 2025 has created a situation in which grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group or initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

8. The NIH meeting blockade has severely and negatively impacted a number of colleges and researchers across the UMCP campus. Ongoing research, planning and implementation of new research projects as well as the recruitment of new graduate students and postdoctoral fellows are impacted. These negative impacts are unique and have the potential for longstanding harm to the UMCP research enterprise, and to the collective biomedical and public health research of the State of Maryland and the United States.

Reliance on NIH Funding

9. In FY 2024, UMCP received funding through the National Institutes of Health ("NIH") to support 148 projects, totaling over $68 million.

10. UMCP receives NIH grants from a variety of institutes within the NIH, including the National Cancer Institute, National Eye Institute, National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis & Musculoskeletal & Skin Diseases, National Institute of Biomedical Imaging & Bioengineering, National Institute of Child Health and Human Development, National Institute of Dental & Craniofacial Research, National Institute of Diabetes & Digestive & Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences,

National Institute of Mental Health, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on Minority Health & Health Disparities, and Office of the Director.

11. Through those NIH grants, UMCP funds 589 employees engaged in the research enterprise.

12. The work done by UMCP on NIH-funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Neuroscience, Chemistry, Psychology, and Human Development and Quantitative Methodology. UMCP contributes to a highly skilled workforce in Science, Technology, Engineering and Mathematics ("STEM") fields, benefiting the Maryland economy.

Typical Timeline and Processes for NIH Grant Awards

13. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity. From there, they are assigned by the Center for Scientific Review to an institute or center with a program interested in funding the proposal and to a study section where the grant application is subjected to peer review and judged on its scientific merit. The study section evaluation is separate and occurs before the assessment by the institute or center. The grant applications in the upper 50% of applications are then given a score by the review panel. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded. The final funding decision is made by the advisory council or board in the institute or center to which the grant has been assigned for support.

14. What constitutes a fundable score is dependent on several factors and differs across institutes and centers. Some publish paylines, meaning the percentiles of grants they will fund. Typically, paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others result in an impact score but not a percentile. Program officers have the latitude to recommend proposals with lower/higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile score of 10% or less as nearly certain to receive funding.

15. After the study section, the grant application is sent to an "advisory council" that each institute or center maintains where the ultimate decision is made on whether to fund the grant. After the advisory council meets, a Notice of Award is issued confirming whether the grant will be funded.

16. The process for competitive renewals of funded proposals is similar. The budget process at UMCP relies upon the NIH grant application, review, and approval cycle. Historically, UMCP has relied on grants being reviewed and scored within 6 to 8 months of submission.

17. Once a grant receives a score, UMCP can consider whether the funding impacts its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

18. Since late January 2025, UMCP has seen severe and unprecedented delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled (in some cases, multiple times), or otherwise not scheduled, resulting in significant delays to grant application and scoring. For example, interruptions in NIH grant notices and reviews for UMCP's School of Public Health have impacted 9 pending NIH grant submissions on which UMCP is the prime recipient, plus four involving UMCP as

subrecipient, totaling 13 pending actions. Principal investigators associated with 2 of 9 submissions were informed that their submissions were pulled from study section review until NIH priorities are realigned. UMCP's College of Behavioral and Social Sciences also has 9 pending grant applications (7 involving UMCP researchers under prime awards, 2 under subawards) awaiting a review date. Three have been postponed with no proposed future date; the others have been moved or postponed to April. In July 2024, UMCP's College of Education submitted a competitive application for continuation of a longitudinal award, the Bucharest Early Intervention Project. The proposal was reviewed by the Child Psychopathology and Developmental Disability study section in October 2024, where it received a score of 12th percentile. Initially, the National Institute of Mental Health Advisory Council was to meet in January 2025, but that meeting was cancelled. It was rescheduled twice (February and March) and cancelled both times. It is now scheduled for May 10, 2025.

19. UMCP has not received formal notice of changes for many of these grants. For others, UMCP has received only a notification that proposals are "paused" or "under review."

20. As of March 29, 2025, UMCP has approximately 200 pending proposals to NIH totaling approximately $354 million.

21. The NIH meeting blockade will severely hamper UMCP's effort to leverage its NIH support to expand the collaborative partnership with the UMB School of Medicine through the newly established St. John Center for Translational Engineering and Medicine ("CTEM"). The CTEM is a collaboration uniting UMCP's A. James Clark School of Engineering's Fischell Department of Bioengineering with UMB's School of Medicine. NIH-funded investigators from both campuses would work at the center supporting the basic science infrastructure. Together, researchers from these distinct disciplines would tackle a broad spectrum of generational health

challenges and drive medical innovations that benefit patients in Maryland and beyond. The current blockade of grant reviews means this CTEM collaboration will be delayed or potentially halted, with over $7 million in research funding at risk for State FY24.

Terminations of NIH Grants

22. Since March 20, 2025, UMCP has received termination notices from NIH with respect to nine grants.

23. The termination notices received as of the date of this declaration are attached as Exhibits 1-14.[1]

24. These terminations will result in the loss of approximately $1,000,000 in obligated research funding to UMCP.

25. The termination notices for these grants provide very little information to explain the terminations, stating only that the research no longer "effectuates agency priorities." In the last 30 years of research administration, UMCP has not seen this language previously used to terminate awards.

26. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. Prior to receipt of the notices, UMCP was not given notice of any opportunity to submit any "corrected" or amended grant materials to align with agency priorities, nor was UMCP advised of any updated "agency priorities" under which its research would be judged.

27. Two of the terminated grants for which UMCP was an awardee include:

a. Research to estimate developmental trends in the prevalence of alcohol use and misuse across groups defined by sexual orientation and gender identity and the intersections of these identities with race/ethnicity, and to explore how sexual and

[1] UMCP email addresses and telephone numbers have been redacted from the exhibits to this declaration.

gender minorities specific and normative adolescent factors collectively shape alcohol use and misuse among sexual and gender minority youth.

b. Research that uses a combination of longitudinal and daily diary methods to examine the prospective associations between intersectional stress, structural oppression, protective and risk factors, and alcohol and other drug use over a 2.5-year period among sexual minority youth of color.

28. Terminated awards where UMCP where subawards that included:

a. Research studying the late diagnosis of autism and how the current diagnostic measures can be improved to be more sensitive to individual characteristics. The termination of this project significantly harms the national and global community of people with autism and their families.

b. Research performing a need assessment for those who suffer biological disorders in sex development (known to be intersex). The termination of this project significantly harms the intersex population, leaving them unacknowledged and untreated.

Comparisons With Past Experience

29. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

30. In past years, administrative actions and functions seemed to operate consistently and reliably, even through such disruptive events as the COVID-19 pandemic. This year, even longstanding, high-performing programs are in limbo.

31. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

32. In UMCP's School of Public Health, many faculty conduct research supported by the NIH, which includes funding for researchers and graduate assistants working on these projects. Previously, receiving a good score assured funding for the research, covering part of the principal investigator's salary and salaries of supporting personnel. Graduate assistants receive funding

commitments as part of their admission packages. Due to NIH funding uncertainty, researcher salaries and graduate assistants' stipends must be budgeted entirely from state funds, posing the risk that support faculty may face layoffs.

33. Concerns related to risks of stop work orders and/or terminations of grants that support shared resources and facilities used by multiple faculty have deterred faculty from participation in multidisciplinary, multi-institutional efforts.

34. Researchers in a university setting must plan their lab budgets and hiring 9 months to 1 year in advance, and for student hires they must plan to provide funding for at least 2 years to cover graduate degree activities. This long-term budget planning is related to the academic year and agency funding cycles. The uncertainty surrounding NIH funding and application processes is impacting researchers' ability to project costs and income, even for the next few months. Thus, the majority of the School of Public Health's departments are reducing doctoral student admissions by at least 50%. In the College of Education, the department most directly affected by uncertainty at NIH has also reduced its doctoral student admissions by 50%, and two doctoral student offers were not made because of the loss of NIH-funding.

35. These delays have forced UMCP to implement bridge funding for dozens of faculty, drawing from limited discretionary resources. UMCP's School of Public Health has been forced to set aside approximately $50,000 to be used to potentially offset this loss of funding. Grant terminations in both the College of Education and the School of Public Health have made it necessary to redirect about $40,000 that could have been used to benefit other students, necessary research, and other activities. Similarly, the College of Behavioral and Social Sciences has had to set aside funds to offset the loss of NIH funding.

36. UMCP may have to pause start-up funding for new hires whose research programs depend on timely NIH awards.

Admissions, Training and Workforce Disruptions

37. UMCP uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

38. Across the institution, UMCP has had to reduce its incoming class of graduate students due to uncertainty over incoming grant funding because of the delays in reviewing and awarding grants by NIH. For example, the Bioengineering Ph.D. program is reducing the number of graduate students it will admit for fall 2025 from about 30 to about 15, due to uncertainty about the NIH grant review process. The Human Development program in the College of Education has reduced the number of graduate student admissions by 50%, due in part to uncertainty about NIH funding. In addition, the Department of Psychology has paused all recruiting for grant-funded research assistant positions given a lack of other institutional funding to support those positions should awards be terminated or not renewed. Admissions to the Biological Sciences program and Neuroscience and Cognitive Science graduate programs have been curtailed severely to just around a fifth of what UMCP normally admits. This will have a severe ripple effect in future years, especially on junior faculty. An associate professor in Biology is unable to recruit graduate students because his NIH council meeting was delayed (his R01 research grant proposal was ranked in the top 1-percentile of all submissions). Finally, the number of doctoral student offers was reduced by 50% in the Department of Human Development and Quantitative Methodology. This reduction was due to a combination of lost or threatened grant revenue and state budget cuts.

39. NIH training/fellowship grants, including T32, R25, and F31 mechanisms, have been affected by review and award delays. These grants provide resources to institutions to train

individuals in certain shortage areas (T32 and R25 grants), and support predoctoral dissertation research (F31 grants). Recruitment for training programs tend to follow the academic year so delays of even 2 months on new awards and non-competing continuations may set a training program back by a full year.

40. UMCP has international postdocs whose visa status is now at risk due to pending NIH awards that were expected to renew this spring.

41. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of UMCP, including by limiting the individuals qualified to conduct certain research. Many units, especially research centers, have limited to no financial resources to provide bridge funding for delayed awards. As such, the University is beginning to issue notices of termination and non-renewal to research professors, research scientists, postdoctoral researchers, and other individuals who support cutting edge public health research.

Concerns About FY25 Funds Being Obligated

42. UMCP is increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

43. Several major proposals from UMCP remain stalled at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time. In some cases, reviews have been rescheduled or reassigned multiple times without explanation.

44. UMCP personnel have heard from peer institutions and agency personnel that NIH is slowing the processing of proposals and awards about certain topic areas due to “heightened scrutiny” or “internal concerns.”

Irreparable Harm

45. The delays and grant terminations discussed above have disrupted ongoing research and have been a setback for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. For example, one graduate assistant in the College of Education was supported by an NIH award that was abruptly terminated. The graduate assistant, who had been involved in the project for two years, was moved to another project but lost important experience in applied psychometric methods. It is uncertain whether funding will continue for the new project, so the student's learning gains will likely again be severely limited. The student will no longer have opportunities to attend conferences, write papers, and otherwise disseminate the findings from the NIH-funded grant work, all of which are important activities for professional learning and career advancement.

46. Some of the studies involve the use of animal test subjects, and a loss of funding results in the loss of those animals, in addition to the loss of the potential scientific benefit and breakthroughs of those studies.

47. Some of these studies had the potential to achieve breakthroughs which would have advanced public health but have now been disrupted. One example is the Bucharest Early Intervention Project ("BEIP"), a landmark decades-long longitudinal study in child development. UMCP's application for continuation of the project is currently delayed at the advisory council level. The BEIP supports the prevention of child neglect and the development of successful families in the United States and it has provided invaluable insights into how psychosocial neglect derails brain development, stress response systems and behavior. BEIP is a study about the effects of severe psychosocial deprivation experienced by children raised in institutions, in which half of these children were removed from institutions early in life and placed into families. They have

now been followed for more than two decades. BEIP findings have shown that even when children do not experience physical abuse, neglect can still have lasting consequences on their brain structure and overall health. And BEIP has identified the factors within the family that contribute to remediation of these early experiences. These findings are especially relevant to children in the United States who experience neglect, highlighting the need for effective policies and support systems to protect families, children and their well-being. As a result of the delay of approval to continue the project, expenditures are on hold and continued delay will result in significant negative impact to the project.

48. Delays in the grant review process and termination of grants have also disrupted community services, student opportunities, and public programs for unknown reasons. For example, a termination of an infectious disease grant and lack of support/uncertainty for support of infectious disease and vaccine research at the National Institute of Allergy and Infectious Diseases has resulted in reductions in the number of graduate students admitted for training in this area and work on a universal flu vaccine. Uncertainty in continued funding has resulted in the closing of a community health clinic and layoff of several staff. The funding focused on infectious disease. But non-communicable, chronic illnesses are prevalent in almost any community where infectious disease is prevalent. Thus, the clinic closure will result in long term chronic health impacts as a result.

49. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted. In the example provided above, uncertainty surrounding the continuity of a student fellowship program has resulted in loss of preventive public health measures for the community as well as interruption in student work. If the funding is permanently

withdrawn, time toward earning a degree is lost and there will be no return on investment for funds spent to date.

50. A summer undergraduate research program, funded continuously by NIH for many years, is also at risk and uncertain of its future. To date, 225 students have completed the program. The vast majority have or are finishing training for health professions serving communities or are on faculty at other universities. Long-term impacts will be felt by communities previously served by ending this pipeline of health care professionals.

51. In another example of harm, a faculty member lost the opportunity to complete her work and contribute to co-authored publications regarding her research on the impacts of the late diagnosis of autism because the grant was terminated. The prime institution was relying on the UMCP faculty member to lead data analysis, so the results of any partial data collection will likely not be analyzed or disseminated. Thus, the researcher's efforts on earlier parts of the project (e.g., advising on study design) may have been wasted.

52. A new assistant professor in Biology had his first solo NIH grant submission cancelled when the Request for Applications was withdrawn. Two Professors in the Department of Cell Biology and Molecular Genetics have a fundable research project (R01) from the National Institute of Allergy and Infectious Diseases at NIH that hasn't received funding due to the cancelation/postponement of an advisory council (now rescheduled for late April). This same issue has delayed funding of NIH exploratory/developmental research (R21) grants with outstanding scores for at least three other early career faculty. The cancellation and delay of NIH study sections for submitted and future grants has cast a pall on cutting-edge health and medical research, leading to restrictions on hiring and spending, further delaying progress.

Conclusion

53. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation, justification or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 1st day of April, 2025, in College Park, Maryland.



Dr. Darryll J. Pines
President and Glenn L. Martin Professor of Aerospace Engineering
University of Maryland College Park

EXHIBIT 1

UNIVERSITY OF MARYLAND

EXHIBIT 1. 5R01HL165686

Bridget Mullan [redacted]

Fwd: STOP WORK ORDER. University of Maryland Subaward 20820

Joeleen Grant-Paterniti [redacted] Fri, Mar 21, 2025 at 9:11 AM
To: Bridget Mullan [redacted]

---------- Forwarded message ---------
From: **Lehner, Kelly** [redacted]
Date: Thu, Mar 20, 2025 at 6:23 PM
Subject: STOP WORK ORDER. University of Maryland Subaward 20820
To: Dyer, Typhanye (UMD) [redacted] Joeleen Grant-Paterniti [redacted]
Cc: Charurat, Manhattan [redacted] SPA-Subteam [redacted] Kinsler, Tony [redacted] Brown, Tony [redacted] Frankenfield, Jill [redacted]

UMB PI: Manhattan Charurat

Subrecipient PI: Typhanye Dyer

Title: Synergistic epidemics of non-communicable diseases, stigma, depression, and material insecurities among sexual and gender minorities living with HIV in Nigeria

Dear Subrecipient:

The University received notice from the US Government on March 20, 2025, that it has terminated award 5R01HL165686-03 in full, effectively immediately.

This email serves as an immediate stop work order on the above referenced Subaward due to this notice.

Further information regarding this matter will be provide shortly.

Kindly confirm receipt of this message at your earliest convenience.

Thank you for your cooperation.

Respectfully,

Kelly

Kelly Lehner

Assistant Director

Sponsored Programs Administration

Office of Research and Development
University of Maryland, Baltimore
620 West Lexington Street, 4th Floor

Baltimore, MD. 21201
[redacted]

EXHIBIT 2

EXHIBIT 2. R01HG012697



03/20/2025

Wendy Beaver
UNIVERSITY OF IOWA
nih@uiowa.edu

Dear Wendy Beaver:

Effective with the date of this letter, funding for Project Number 5R01HG012697-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Deanna Ingersoll, Chief Grants Management Officer, National Human Genome Research Institute
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 3

EXHIBIT 3. 5F32AA030194

UNIVERSITY OF MARYLAND

Danette Boone [redacted]

Grant Termination Notification

1 message

Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov> Fri, Mar 21, 2025 at 12:34 PM
To: "dboone14@umd.edu" [redacted]

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

Danette Boone

Univ Of Maryland, College Park

[redacted]

Dear Danette Boone:

Effective with the date of this letter, funding for Project Number 5F32AA030194-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 4

UNIVERSITY OF MARYLAND

ORA Mail (SHARED) [redacted]

NoA: 5F32AA030194-03 PI: Meg Bishop

1 message

eraNotifications@mail.nih.gov <eraNotifications@mail.nih.gov> Wed, Mar 26, 2025 at 12:13 AM
To: [redacted]

Grant Number: 5F32AA030194-03
Principal Investigator: Bishop, Meg
Project Title: Sexual orientation, gender identity, and alcohol use: A multi-method analysis of developmental differences and key mechanisms
Institution: UNIVERSITY OF MARYLAND
CFDA: 93.273
OC: 41013
PCC: AE FD
Award Issue Date: 03/25/2025
Grants Management Officer: Fox, Judy
Program Official: Freeman, Robert
Grants Specialist: Stringfield, Donna

This is an automated notification - Please do not reply to this message.

5F32AA030194-03-Noa.pdf
221K

EXHIBIT 5

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Notice of Award
FAIN# F32AA030194
Federal Award Date
03/25/2025

308472-00001

Recipient Information

1. Recipient Name
UNIVERSITY OF MARYLAND, COLLEGE PARK
3112 LEE BUILDING
COLLEGE PARK, MD 20742

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1520710851A1

4. Employer Identification Number (EIN)
520710851

5. Data Universal Numbering System (DUNS)
790934285

6. Recipient's Unique Entity Identifier
NPU8ULVAAS23

7. Project Director or Principal Investigator
Meg Bishop, PHD

mbishop3@umd.edu
917-817-7856

8. Authorized Official
Bridget Mullan
bmullan@umd.edu
301-405-8061

Federal Agency Information

9. Awarding Agency Contact Information
Donna Stringfield

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
donna.stringfield@nih.gov
(301) 443-3851

10. Program Official Contact Information
Robert Freeman
Health Scientist Administrator
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
rfreeman@mail.nih.gov
301443-8820

Federal Award Information

11. Award Number
5F32AA030194-03

12. Unique Federal Award Identification Number (FAIN)
F32AA030194

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Sexual orientation, gender identity, and alcohol use: A multi-method analysis of developmental differences and key mechanisms

15. Assistance Listing Number
93.273

16. Assistance Listing Program Title
Alcohol Research Programs

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$76,047
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$76,047
26. Project Period Start Date 09/01/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$215,194

28. Authorized Treatment of Program Income

29. Grants Management Officer - Signature
Judy Fox

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

SECTION I – AWARD DATA – 5F32AA030194-03 REVISED

Principal Investigator(s):
Meg Bishop, PHD

Award e-mailed to: oraa@umd.edu

Fellow's e-mail:
Meg Bishop mbishop3@umd.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIV OF MARYLAND, COLLEGE PARK in support of the above referenced project. This award is pursuant to the authority of 42 USC 288 42 CFR 66 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Alcohol Abuse And Alcoholism of the National Institutes of Health under Award Number F32AA030194. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Judy Fox
Grants Management Officer
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$12,400
Other	$1,763

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Stipends	$61,884
Federal Direct Costs	$76,047
Total Award	$76,047
Total Amount of Federal Funds Authorized (Federal Share)	$76,047
TOTAL FEDERAL AWARD AMOUNT	$76,047
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$76,047	$76,047

Fiscal Information:

Payment System Identifier:	1520710851A1
Document Number:	FAA030194A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
AA	8470473	$76,047

NIH Administrative Data:
PCC: AE FD / **OC:** 41013 / **Released:** 2025-03-25
Award Processed: 03/26/2025 00:13:40 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5F32AA030194-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm.

SECTION III – STANDARD TERMS AND CONDITIONS – 5F32AA030194-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain
references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) F32AA030194. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Fellowships that terminate early and awards in the final year are subject to NIH Closeout requirements. See Sections 8.6 and 11.2.11 of the NIH Grants Policy Statement Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final Federal Financial Report (FFR) (SF 425) on expenditures is not required for fellowships. NIH will close the fellowship using the last recorded cash drawdown level in the Payment Management System (PMS).

A Termination Notice is required in lieu of a final progress report. The termination notice must be submitted within 30 days of the termination date even if the fellow is not available for signature. In all cases, the information on the form must be verified by the sponsor and an institutional business official. The lack of timely and accurate information on this form could adversely affect data collected associated with aggregate NRSA support and the payback process. All Termination Notices for individual fellowships are required to be submitted electronically using the eRA Commons xTrain application.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's

expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

An individual's initial 12 months of NRSA postdoctoral support is subject to the payback service requirements of the authorization cited above.

Fellows are required to notify the awarding unit as soon as they are aware of any possible change in plans regarding their fellowship support.

Childcare Costs
If this award includes childcare costs of $3,000, the funds are restricted and may not be used for any other purpose without prior approval.

SECTION IV – AA SPECIFIC AWARD CONDITIONS – 5F32AA030194-03 REVISED

REVISION: It is the policy of NIH not to prioritize gender identity. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, this project is terminated. The University of Maryland (college Park) may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant. As stated in section III of this NoA, a termination notice is due within 30 days of the termination date.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

STIPEND LEVELS: Stipends must be paid in accordance with stipend levels established by NIH, which are based on a 12-month full-time training appointment. In the event of early termination, the stipend will be prorated per the amount of time spent in training, and NIH will issue a revised Notice of Research Fellowship Award.

No departure from the standard stipend provided by NIH under this fellowship award may be negotiated by the sponsoring institution with the fellow. This award reflects the stipend level currently in effect as stipulated in the April 23, 2024 NIH Guide Notice NOT-OD-24-104. (See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html)

TERMINATION: This fellowship is entering its final year of support.
NRSA policy requires the electronic submission of a Termination Notice (PHS 416-7) via the eRA Commons xTrain system immediately following the termination of support, whether support ends on the project period end date reflected on this Notice of Award or before the established end date if the fellow early terminates.

NOTE: As of January 1, 2011, the National Institutes of Health (NIH) requires the use of the eRA Commons xTrain system to electronically prepare and submit the PHS 416-7 Termination Notice for Kirschstein-NRSA fellowships. Paper termination notices will not be accepted. Paper submissions will be considered

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noncompliant. To comply with this requirement, potential xTrain users are encouraged to review the training resources and instructions for using the system available on the eRA Commons page at https://www.era.nih.gov/erahelp/xtrain/

INSTITUTIONAL ALLOWANCE: The Institutional Allowance is awarded at the current amount stipulated in the April 23, 2024 NIH Guide Notice NOT-OD-24-104. (See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html)

Please be reminded, in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/policy.htm#gps), if an individual fellow is not in a training status for more than 6 months of the award year, only one-half of that year's institutional allowance may be charged to the grant.

SPREADSHEET SUMMARY
AWARD NUMBER: 5F32AA030194-03 REVISED

INSTITUTION: UNIV OF MARYLAND, COLLEGE PARK

Budget	Year 3
Institutional Allowance	$12,400
Other	$1,763
Stipends	$61,884
TOTAL FEDERAL DC	$76,047
TOTAL FEDERAL F&A	$0
TOTAL COST	$76,047

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EXHIBIT 6

EXHIBIT 4. 1OT2 OD035669

National Institutes of Health
Office of Extramural Research

March 21, 2025

Lindsay Lynch
Asian Community Health Coalition
[redacted]

Dear Lindsay Lynch:

Effective with the date of this letter, funding for Project Number 1OT2 OD035669-01 is hereby terminated pursuant to the terms of the OT award agreement. This letter constitutes a notice of termination.[1]

NIH has determined that a termination is in the Government's best interest, because this award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) awards and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[2] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities. To comply with the OT award conditions, the Division of Other Transactions Management will set up an official meeting to consultation to discuss the orderly closeout of the OT project.

Costs resulting from financial obligations incurred after termination are not allowable.[3] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[4]

[1] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[2] 2024 Policy Statement at IIA-156.
[3] *See* 2 C.F.R. § 200.343 (2024).
[4] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

Administrative Appeal

You may object and provide information and documentation challenging this termination.[5] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[6]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[7]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[8]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls
Director, Office of Policy for Extramural Research Administration, OER, NIH

[5] *See* 45 C.F.R. § 75.374.
[6] See 42 C.F.R. Part 50, Subpart D
[7] 11 *Id.* § 50.406(a)
[8] 12 *Id.* § 50.406(b)

EXHIBIT 7

EXHIBIT 5. R01AA029989

UNIVERSITY OF MARYLAND

Cathy Cuff [redacted]

Fwd: Grant Termination Notification - GR012500/309588-00001

1 message

Dwayna K Dawkins [redacted] Mon, Mar 24, 2025 at 3:23 PM
To: Cathy Cuff [redacted]

Award# GR012500/309588-00001
Add Time: Y/N - N
Add Money: Y/N - N
New Child Account Needed: Y/N -

Notes: (e.g. - adding time and money, there is cost share, special invoicing notes)

High Priority

This notification terminates this project. See department contacts below

Departmental Business Person - William (Bill) Liden [redacted]
Chair Michael Dougherty [redacted]
Dean Susan Rivera [redacted]

You can also include Rebecca Hunsaker [redacted]

Thank you,

Dwayna K Dawkins, M.S, M.A
Contract Administrator | Office of Research Administration
University of Maryland | 7809 Regents Drive, 3112 Lee Bldg | College Park, MD 20742
[redacted]

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <michelle.bulls@nih.gov>
Date: Fri, Mar 21, 2025 at 12:35 PM
Subject: Grant Termination Notification
To: [redacted]

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

Bullock, Rose

Univ Of Maryland, College Park

[redacted]

Dear Bullock, Rose:

Effective with the date of this letter, funding for Project Number 5R01AA029989-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 5/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 8

UNIVERSITY OF MARYLAND

ORA Mail (SHARED) [redacted]

NoA: 5R01AA029989-04 PI: Ethan Mereish

ORA Mail (SHARED) [redacted] Tue, Mar 25, 2025 at 1:10 PM
Draft To: [redacted]

Institutional Proposal Number:25042337

Thank you,

Office of Research Administration
University of Maryland
301-405-6269

---------- Forwarded message ---------
From: <eraNotifications@mail.nih.gov>
Date: Tue, Mar 25, 2025 at 12:07 AM
Subject: NoA: 5R01AA029989-04 PI: Ethan Mereish
To: [redacted]

Grant Number: 5R01AA029989-04
Principal Investigator: Mereish, Ethan H.
Project Title: Long-term and Daily Associations among Intersectional Minority Stress, Structural Oppression, and Alcohol Use and Misuse among Sexual Minority Adolescents of Color
Institution: UNIVERSITY OF MARYLAND
CFDA: 93.273
OC: 41025
PCC: AE VD
Award Issue Date: 03/25/2025
Grants Management Officer: Fox, Judy
Program Official: Ruffin, Beverly
Grants Specialist: Zeigler, Kelvin

This is an automated notification - Please do not reply to this message.

5R01AA029989-04-Noa.pdf
249K

EXHIBIT 9

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Notice of Award
FAIN# R01AA029989
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF MARYLAND, COLLEGE PARK
3112 LEE BUILDING
COLLEGE PARK, MD 20742

2. Congressional District of Recipient
04

3. Payment System Identifier (ID)
1520710851A1

4. Employer Identification Number (EIN)
520710851

5. Data Universal Numbering System (DUNS)
790934285

6. Recipient's Unique Entity Identifier
NPU8ULVAAS23

7. Project Director or Principal Investigator
Ethan H. Mereish, PHD
Associate Professor
emereish@umd.edu
301-405-5874

8. Authorized Official
Rose Bullock
bullockr@umd.edu
301-405-6177

Federal Agency Information

9. Awarding Agency Contact Information
Kelvin Zeigler

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
zeiglerk@mail.nih.gov
301-443-1119

10. Program Official Contact Information
Beverly Ruffin

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
beverly.ruffin@nih.gov
301-443-0281

Federal Award Information

11. Award Number
5R01AA029989-04

12. Unique Federal Award Identification Number (FAIN)
R01AA029989

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Long-term and Daily Associations among Intersectional Minority Stress, Structural Oppression, and Alcohol Use and Misuse among Sexual Minority Adolescents of Color

15. Assistance Listing Number
93.273

16. Assistance Listing Program Title
Alcohol Research Programs

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/01/2024 – **End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$729,606
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$729,606
26. Project Period Start Date 05/10/2022 – **End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,165,921

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Judy Fox

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

SECTION I – AWARD DATA – 5R01AA029989-04 REVISED

Principal Investigator(s):
Ethan H. Mereish, PHD

Award e-mailed to: oraa@umd.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIV OF MARYLAND, COLLEGE PARK in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Alcohol Abuse And Alcoholism of the National Institutes of Health under Award Number R01AA029989. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Judy Fox
Grants Management Officer
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$75,295

Fringe Benefits	$13,979
Personnel Costs (Subtotal)	$89,274
Other	$401,124
Federal Direct Costs	$490,398
Federal F&A Costs	$239,208
Approved Budget	$729,606
Total Amount of Federal Funds Authorized (Federal Share)	$729,606
TOTAL FEDERAL AWARD AMOUNT	$729,606
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$729,606	$729,606

Fiscal Information:
Payment System Identifier: 1520710851A1
Document Number: RAA029989B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
AA	8470415	$729,606

NIH Administrative Data:
PCC: AE VD / **OC**: 41025 / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:07:17 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AA029989-04 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AA029989-04 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AA029989. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AA SPECIFIC AWARD CONDITIONS – 5R01AA029989-04 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: It is the policy of NIH not to prioritize gender identity. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, this project is terminated. The University of Maryland (College Park) may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you

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mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

This award is issued in accordance with NIH FY24 Fiscal Policies (see NIH Guide Notice NOT-OD-24-109 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-109.html including salary limitations as indicated below.

SALARY LIMITATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Current salary cap levels can be found at https://grants.nih.gov/grants/policy/salcap_summary.htm.

The research supported by this award involves a population of **human subjects identified as "vulnerable".** Investigators who conduct research involving vulnerable populations, including pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations (https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm).

INFORMATION: This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (see http://grants.nih.gov/grants/policy/policy.htm#gps).

NIAAA DATA ARCHIVE (NIAAADA) DATA SHARING REQUIREMENT: This award is subject to the data sharing guidance outlined in NOT-AA-23-002 (https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-002.html).

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AA029989-04 REVISED

INSTITUTION: UNIV OF MARYLAND, COLLEGE PARK

Budget	Year 4
Salaries and Wages	$75,295
Fringe Benefits	$13,979
Personnel Costs (Subtotal)	$89,274
Other	$401,124
TOTAL FEDERAL DC	$490,398
TOTAL FEDERAL F&A	$239,208
TOTAL COST	$729,606

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	54.5%
F&A Cost Base 1	$438,914
F&A Costs 1	$239,208

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EXHIBIT 10

EXHIBIT 6. R01HD114134

Children's National

111 Michigan Ave NW
Washington, DC 20010-2916
ChildrensNational.org

March 21, 2025

Katie Kemmerer
University of Maryland
Office of Research Administration
3112 Lee Building, 7809 Regents Drive
College Park, MD 20742-5141

Re: TERMINATION - Cost Reimbursable Subaward Agreement regarding study titled "Equitable Measurement of Care Disparities and Needs in Intersex Youth/Youth with Variations in Sex Development" dated June 13, 2024
Contract Number: **30008154-05**

Dear Office of Research Administration:

This letter serves as notice that Children's Research Institute ("CRI") hereby terminates the above-referenced Cost Reimbursable Subaward Agreement ("Agreement") in accordance with the Agreement terms and provisions, **effective March 20, 2025**, pursuant to early termination of the Prime Award.

University of Maryland ("Subrecipient") agrees to provide all results and findings, data collected, generated or disseminated by Subrecipient to CRI to date of termination, and to return all confidential information to CRI.

If you have any questions, please don't hesitate to contact us via email subs@childrensnational.org.

Sincerely,

Nellie Falconett
Agreements Manager, Grants and Contracts
Children's Research Institute/Children's National Medical Center
1 Inventa Place, West Tower, Floor 3
Silver Spring, MD 20910

EXHIBIT 11

EXHIBIT 7. R01 MH138335



March 20, 2025

Stephanie Boman
The Ohio State University
[redacted]

Dear Stephanie Boman:

Effective with the date of this letter, funding for Project Number 1R01 MH138335-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on January 1, 2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 17:02:10 -04'00'

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 12

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF MENTAL HEALTH

Notice of Award
FAIN# R01MH138335
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
OHIO STATE UNIVERSITY, THE
1960 KENNY RD
COLUMBUS, OH 43210

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
1316025986A1

4. Employer Identification Number (EIN)
316025986

5. Data Universal Numbering System (DUNS)
832127323

6. Recipient's Unique Entity Identifier
DLWBSLWAJWR1

7. Project Director or Principal Investigator
CHRISTINA DYAR, PHD (Contact)
Assistant Professor
dyar.13@osu.edu
614-688-0623

8. Authorized Official
Stephanie Boman
boman.18@osu.edu

Federal Agency Information

9. Awarding Agency Contact Information
Lauren Nicole Cummings
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
lauren.cummings@nih.gov

10. Program Official Contact Information
Eric Rousseau Murphy

NATIONAL INSTITUTE OF MENTAL HEALTH
eric.murphy@nih.gov
(301) 443-9230

Federal Award Information

11. Award Number
1R01MH138335-01

12. Unique Federal Award Identification Number (FAIN)
R01MH138335

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Bisexual adolescents' and young adults' risk for depression and suicidal ideation: Developmental trajectories, risk and protective factors, and underlying mechanisms

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 01/01/2025 **– End Date** 03/20/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$815,881
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$815,881
26. Project Period Start Date 01/01/2025 **– End Date** 03/20/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$815,881

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Theresa R. Jarosik

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R01MH138335-01 REVISED

Principal Investigator(s):
CHRISTINA DYAR (contact), PHD
Brian Feinstein, PHD

Award e-mailed to: NIHaward@osu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to OHIO STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R01MH138335. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Theresa R. Jarosik
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$200,422

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Fringe Benefits	$66,876
Personnel Costs (Subtotal)	$267,298
Materials & Supplies	$5,400
Travel	$5,000
Other	$66,000
Subawards/Consortium/Contractual Costs	$231,432
Federal Direct Costs	$575,130
Federal F&A Costs	$240,751
Approved Budget	$815,881
Total Amount of Federal Funds Authorized (Federal Share)	$815,881
TOTAL FEDERAL AWARD AMOUNT	$815,881
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$815,881	$815,881

Fiscal Information:
Payment System Identifier: 1316025986A1
Document Number: RMH138335A
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025
MH	8022575	$815,881

NIH Administrative Data:
PCC: B4-TBD / **OC**: 41021 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:10:33 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MH138335-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MH138335-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-

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research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MH138335. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted

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electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R01MH138335-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION #1
TERMINATION
It is the policy of NIH not to prioritize research activities based on gender identity as it no longer effectuates agency priorities. Therefore, this project is terminated. OHIO STATE UNIVERSITY may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

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NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

SUPERSEDES NOTICE OF AWARD ISSUED 12/23/2024.

AWARD NOTICE:
This award has been made in response to the application submitted under the Notice of Funding Opportunity Announcement PA-20-185 which can be referenced at: https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html and NOSI NOT-OD-22-166 and https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-166.html

ADMINISTRATIVE REDUCTION:
In order to meet Institute program objectives within Fiscal Year 2025 budget constraints, years 2 and 3 have been reduced by 10% and 5%, respectively.

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with Rosalind Franklin University of Medicine and Science, University of Maryland and Washington University in St. Louis. Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

HUMAN SUBJECTS RESEARCH:
This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 12/11/2024. It is expected that 78 of the 500 total projected participants will be recruited by 8/01/2025. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

DATA SHARING PLAN:
This award is subject to the data sharing guidance outlined in NOT-MH-23-100 and can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-23-100.html. The

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recipient will adhere to the resource and data sharing plan in the application. Dissemination of study data will be in accordance with the accepted data sharing plan. **Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing."** Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Complete NIMH data sharing terms and conditions can be found at https://nda.nih.gov/nda/sharing-regimen. Instructions are available at http://grants.nih.gov/grants/rppr/index.htm. Complete guidelines on data sharing are available at https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/research-covered-under-the-data-management-sharing-policy#after.

DATA AND SAFETY MONITORING:
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

OTHER SUPPORT TIME COMMITMENT:
Commitment overlap is not permitted and occurs when an individual's time commitment exceeds 100 percent (I.e., 12 person months), whether or not salary is requested. Therefore, no individual's time commitment may exceed 100 percent. Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1
DMS Costs	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01MH138335-01 REVISED

INSTITUTION: OHIO STATE UNIVERSITY

Budget	Year 1
Salaries and Wages	$200,422
Fringe Benefits	$66,876
Personnel Costs (Subtotal)	$267,298

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Materials & Supplies	$5,400
Travel	$5,000
Other	$66,000
Subawards/Consortium/Contractual Costs	$231,432
TOTAL FEDERAL DC	$575,130
TOTAL FEDERAL F&A	$240,751
TOTAL COST	$815,881

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	57.5%
F&A Cost Base 1	$418,698
F&A Costs 1	$240,751

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EXHIBIT 13

EXHIBIT 8. R56AG079510

UNIVERSITY OF MARYLAND

Bridget Mullan [redacted]

Notice of Termination - UCSF Subaward 14965sc

Hussein, Karim [redacted] Tue, Mar 25, 2025 at 5:31 PM
To: [redacted]
Cc: "Schechter, Shannon" [redacted] "Park, Van" <[redacted]>, "Galanos, Nathan" <[redacted]>
"Fernandez, Frank" [redacted]

Greetings,

Please find attached a termination notice from NIH, effective 3/21/25. This applies to your subaward # 14965sc.

UCSF will be appealing the decision, but please be advised that until we receive a decision on the appeal, expenses under this project after 3/21/25 may not be reimbursed.

We will keep you informed if anything changes.

Regards,

Karim

Karim Hussein, JD (he/him)

Manager, Subcontracts | Office of Sponsored Research

University of California, San Francisco

[redacted] | [redacted]

UCSF

EO_TERMN_A142269_PARK_V_NIH_NIA_1R56AG079510_01A1_REVISED.pdf
170K

EXHIBIT 14

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R56AG079510
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425
SAN FRANCISCO, CA 94103

2. Congressional District of Recipient
11

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
Van My Ta Park, PHD

Van.Park@ucsf.edu
141-551-4331

8. Authorized Official
Magdalene Cho

Federal Agency Information

9. Awarding Agency Contact Information
Ryan Blakeney

NATIONAL INSTITUTE ON AGING
blakeneyr@mail.nih.gov
301-451-9802

10. Program Official Contact Information
FRANK Bandiera

NATIONAL INSTITUTE ON AGING
frank.bandiera@nih.gov
301-496-3131

Federal Award Information

11. Award Number
1R56AG079510-01A1

12. Unique Federal Award Identification Number (FAIN)
R56AG079510

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Asian Americans & Racism: Individual and Structural Experiences (ARISE)

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/21/2023 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$3,432,146
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$3,432,146
26. Project Period Start Date 09/21/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,432,146

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Philip E. Smith

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R56AG079510-01A1 REVISED

Principal Investigator(s):
Van My Ta Park, PHD

Award e-mailed to: cgrasteam@ucsf.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R56AG079510. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$621,610
Fringe Benefits	$233,897

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Personnel Costs (Subtotal)	$855,507
Consultant Services	$77,320
Materials & Supplies	$25,834
Travel	$13,645
Other	$401,301
Subawards/Consortium/Contractual Costs	$1,177,144
Publication Costs	$3,639
Federal Direct Costs	$2,554,390
Federal F&A Costs	$877,756
Approved Budget	$3,432,146
Total Amount of Federal Funds Authorized (Federal Share)	$3,432,146
TOTAL FEDERAL AWARD AMOUNT	$3,432,146
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$3,432,146	$3,432,146

Fiscal Information:
Payment System Identifier: 1946036493A6
Document Number: RAG079510A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
AG	8033157	$3,432,146

NIH Administrative Data:
PCC: 2CEPIFB / **OC**: 41021 / **Released**: 03/21/2025
Award Processed: 03/24/2025 12:03:20 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R56AG079510-01A1 REVISED

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SECTION III – STANDARD TERMS AND CONDITIONS – 1R56AG079510-01A1 REVISED

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a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to

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report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R56AG079510. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R56AG079510-01A1 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

It is the policy of NIH not to prioritize DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.. Therefore, this project is terminated. The UNIVERSITY OF CALIFORNIA, SAN FRANCISCO may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly

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closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes Notice of Award issued 10/17/2023. Previous Terms and Conditions apply:

The sole purpose of this revised Notice of Award is to remove the restriction of funds due to the receipt and approval of Other Support for key personnel.

Supersedes Notice of Award issued 9/20/2023. Previous Terms and Conditions apply:

This Bridge award provides limited interim research support. This project is awarded for a period of one year.

See: https://grants.nih.gov/grants/funding/r56.htm

R56 recipients are encouraged to submit a revision of their original competing application to be considered for future funding. Applicants are reminded that the limitations on time and the number of amendments described at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html apply to all subsequent revisions. A Final Research Performance Progress Report, Final Financial Report, and Final Invention Statement will be required 120 days after the end of the R56 grant period if a revised competing application is not funded.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm

In order to meet Institute Program objectives, direct costs awarded have been adjusted to a level determined to be compatible with the approved scope of the grant while also meeting NIA cost management objectives.

This award includes funds awarded for consortium activity with University of California, Davis in the amount of $356,339 ($222,480 direct costs + $133,859 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of California, Irvine in the amount of $509,470 ($324,503 direct costs + $184,967 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of California, Los Angeles in the amount of $38,229 ($24,506 direct costs + $13,723 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Maryland, College Park in the amount of $109,412 ($70,817 direct costs + $38,595 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Minnesota in the amount of $163,694 ($105,609 direct costs + $58,085 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced

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section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

SPREADSHEET SUMMARY
AWARD NUMBER: 1R56AG079510-01A1 REVISED

INSTITUTION: The Regents of the UCSF

Budget	Year 1
Salaries and Wages	$621,610
Fringe Benefits	$233,897
Personnel Costs (Subtotal)	$855,507
Consultant Services	$77,320
Materials & Supplies	$25,834
Travel	$13,645
Other	$401,301
Subawards/Consortium/Contractual Costs	$1,177,144
Publication Costs	$3,639
TOTAL FEDERAL DC	$2,554,390
TOTAL FEDERAL F&A	$877,756
TOTAL COST	$3,432,146

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	61.5%
F&A Cost Base 1	$1,427,246
F&A Costs 1	$877,756

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EXHIBIT 19

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF DR. BRUCE E. JARRELL

I, Bruce E. Jarrell, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am President of the University of Maryland, Baltimore ("UMB"), a constituent institution of the University System of Maryland ("USM"), the State of Maryland's public system of higher education. As President, I have statutory responsibility and accountability to the USM Board of Regents for developing the mission and successful conduct of UMB and for the supervision of each of UMB's departments. I am familiar with the information in the statements set forth below through personal knowledge or information provided to me in connection with my duties.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am President at UMB. This is a position I have held since 2020. From 2012 until my appointment as President I served as UMB's chief academic and research officer and senior

vice president, holding the title of Provost and Executive Vice President. I previously served as the institutional official for human research protection and animal research protections and have remained actively involved in research and medical student education throughout my career. I joined UMB in 1997 as chair of the University of Maryland School of Medicine's Department of Surgery.

4. UMB's mission is to improve the human condition and serve the public good of Maryland and society at large through education, research, clinical care, and service.

5. Opened in 1807, UMB is Maryland's public health, law, and human services university, dedicated to excellence in education, research, clinical care, and service. UMB enrolls nearly 6,700 students in six nationally ranked professional schools — dentistry, law, medicine, nursing, pharmacy, and social work — and an interdisciplinary School of Graduate Studies. The University offers 97 doctoral, master's, baccalaureate, and certificate programs and confers most of the professional practice doctoral degrees awarded in Maryland. UMB employs more than 8,200 employees working toward fulfillment of UMB's mission.

6. UMB is a thriving academic health center combining cutting-edge biomedical research and exceptional patient care. UMB's extramural funding totaled $638 million in Fiscal Year 2024, and each tenured/tenure-track faculty member brings $1.45 million in research grants, on average, into UMB every year.

7. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections and advisory council meetings. NIH's abrupt cessation of NIH advisory council meetings in January 2025 created a situation in which grant proposals submitted for funding have remained unfunded indefinitely. These are grants that were previously evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific

review group or initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute or center within NIH.

8. The NIH meeting blockade severely impacts UMB by creating a domino effect of delays for review of newly submitted grant proposals, for review of previously submitted grant proposals, for notices of award of grant proposals that are in the queue for award, and for extensions of already approved awards. These delays create lapses in funding and make it impossible for UMB to plan and budget for personnel whose positions are funded, directly or indirectly, by extramural funding. Most of these personnel hold positions that require lengthy notice periods.

Reliance on NIH Funding

9. In fiscal year 2024, UMB received funding through the National Institutes of Health ("NIH") to support 446 active NIH awards, totaling $213.9 million, and an additional 299 projects and $34.2 million in NIH pass-through funding.

10. UMB receives NIH grants from 22 institutes or centers within NIH, including National Institute of Allergy and Infectious Diseases (NIAID), National Cancer Institute (NCI), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS), National Institute on Drug Abuse (NIDA), National Institute on Aging (NIA), National Institute of Mental Health (NIMH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institute of General Medical Sciences (NIGMS), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Fogarty International Center (FIC), National

Institute on Alcohol Abuse and Alcoholism (NIAAA), National Eye Institute (NEI), National Library of Medicine (NLM), National Institute on Deafness and Other Communication Disorders (NIDCD), National Human Genome Research Institute (NHGRI), National Institute on Minority Health and Health Disparities (NIMHD), National Center for Complementary and Integrative Health (NCCIH), National Institute of Environmental Health Sciences (NIEHS), National Institute of Biomedical Imaging and Bioengineering (NIBIB).

11. Through those NIH awards, UMB funds approximately 955 FTEs (full-time equivalent positions), and through NIH passthrough awards, UMB funds an additional 161 FTEs.

12. The work done by UMB on NIH-funded projects provides education and training in diseases such as cancer, metabolic disorders like diabetes, vaccinology, cardiovascular disease, neuroscience, schizophrenia, gastroenterology, aging, immunity, clinical and translational research, research ethics and integrity, oral and craniofacial health, muscle biology, immunology, infectious disease, and physician-scientist training.

13. UMB contributes to a highly skilled workforce in Science, Technology, Engineering and Mathematics ("STEM") fields, benefiting Maryland's economy.

Typical Timeline and Processes for NIH Grant Awards

14. Through my work as President, and previously as chief academic and research officer, I have a strong understanding of the NIH grant process, grounded in over 25 years of experience in research-related roles.

15. Sponsored Programs Administration at UMB works with researchers to submit grant applications and tracks grant applications and processes awards. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity. From there, they are assigned to a "study section" where the application is subjected to peer review

and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors, as every institute is different. Most of the standing study section reviews result in an impact score and percentile score for each proposal. Others (e.g., special emphasis panels and non-CSR reviews) result only in an impact score. Impact scores run from 10 to 90; 10 is best (i.e., high impact). NIH's published grant review processes indicate that applications receiving an impact score of 10 to 30 are most likely to be funded. Percentile scores run from 1 to 99; a lower percentage indicates a better score. Researchers would consider a percentile score of less than 10% as virtually certain to receive funding.

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more common for a grant that has been funded in the past to be renewed.

19. The budget process at UMB relies upon the NIH grant application, review, and approval cycle. Historically, UMB has relied on grants being reviewed and scored within 3 months of submission and awards starting 8 to 9 months after submission.

20. Once a grant receives a score, UMB can consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

21. Since late January 2025, UMB has seen severe and unprecedented delays in the processing of NIH grant applications. Researchers have had their grant application study sections

and advisory councils canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

22. UMB has not received formal notice of changes to the review process or evaluation criteria or adoption of changes in agency priorities.

23. As of March 28, 2025, UMB has approximately 380 proposals totaling $1.04 billion awaiting NIH study section review.

24. As of March 28, 2025, UMB has 32 proposals totaling $21.4 million that received fundable scores awaiting NIH advisory council and Notice of Award.

25. As of March 28, 2025, UMB has 10 proposals totaling $28.1 million which have received fundable scores and have been previously reviewed by NIH advisory council but remain listed as Pending Administrative Review and another 2 proposals totaling $9.4 million that have received fundable scores and were reviewed by NIH advisory council in September 2024 but have not even been placed in the Pending Administrative Review status. When UMB has inquired, the response provided indicated that actions are "paused" or "under review."

26. As of March 28, 2025, UMB has 44 proposals totaling $33.2 million that received possibly fundable scores awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

27. As of March 28, 2025, UMB has received notices of termination of 11 NIH awards including one passthrough award.

28. The terminations received as of March 28, 2025 are attached as Exhibits 1-11.[1]

29. These terminations will result in the loss of approximately $15 million in research money to UMB.

[1] UMB email addresses and telephone numbers have been redacted from the exhibits to this declaration.

30. The termination notices for these grants have provided very little information to explain the terminations, stating only that the research no longer "effectuates agency priorities." In my more than 25 years working at UMB, I have not seen this language previously used to cancel grants.

31. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, UMB was not given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities, nor was it advised of any new priorities that grant materials should address.

32. The terminated grants include:

a. 5R01DE032225-02: Research into the biological differences in brain mechanisms between males and females in mediating chronic orofacial and comorbid pain conditions. A key objective of the project was to explore the role of testosterone in modulating pain responses and brain circuitries involved in endogenous pain modulation. Testosterone is a crucial gonadal hormone with significant implications for pain management strategies in both men and women. This area of research is vastly understudied, yet it holds high translational potential for developing effective pain management strategies. The project's rigorous methodology and significant research potential earned it the highest score in the study section. This underscores the project's potential to drive meaningful advancements in the understanding of sex differences in chronic pain and the development of effective pain management strategies.

b. 3R01MD019029-02S1 and 5R01MD019029-02: Using modern psychometric techniques and economic indicators, the research associated with these two grants was aimed at assessing how the wealth gap, influenced by racial and ethnic inequalities, affects health outcomes across different groups. The overall positive impact of the tool will be its use in research settings to find effective interventions to reduce racial health inequities.

c. 5UG1HD113162-02: In collaboration with NIH's AHISA, this implementation science study tests a youth-tailored intervention to improve HIV prevention and HIV care continuum for vulnerable youths at risk of HIV or living with HIV across West, East, and Southern African countries. Centralized resources for regulatory compliance, data management, data quality, and data analysis across the clinical research performing sites promote efficiency and quality.

d. 5R01HL165686-03: There is an increasing burden of HIV-associated noncommunicable (HIVNCD) diseases globally which often cluster among populations facing persistent social and economic inequalities. This research examines population-level clustering of systemic factors (stigma, depression, material insecurity, polysubstance use, intimate partner violence, and police and other violence) and HIVNCD in Nigeria. It will provide critical data for informing the development of integrated, multilevel interventions intended to remediate disparities in HIVNCD and their outcomes.

e. 3D43TW012274-03, -03S1, -03S2, and -03S3: These four grants supported the Integrated Networks of Scholars in Global Health Research Training (INSIGHT) which is a consortium formed among UMB, the University of Alabama at

Birmingham, the Baylor College of Medicine, and the University of Pittsburgh. The work includes 169 faculty members across a multidisciplinary and multi-institutional consortium that supports training for the next generation of global health scholars from the United States and low- and middle-income countries through mentored research experiences at 24 established partner institutions across 19 countries in Africa, Asia, and Latin America and the Caribbean. Strong emphases are on a broad range of global health research areas, including combatting the global HIV epidemic and associated co-morbidities, emerging and re-emerging infectious diseases, non-communicable diseases, and mental health.

f. 5R01MH134721-02: Based on the documented, continued disproportionate rates of HIV infection among certain populations, this is a public health project aimed at identifying scalable interventions to support pre-exposure prophylaxis use.

g. 1U19AI171443-01: This pass-through grant related to the multidisciplinary Center for Antiviral Medicines & Pandemic Preparedness which focuses on development of antiviral drugs to combat coronaviruses and other viruses with pandemic potential.

Comparisons Across Administrations

33. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

34. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

35. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

36. These delays make it impossible for UMB to forecast its budget and academic programming.

37. These delays force UMB to use bridge funding for salaries of multiple faculty members, drawing from limited discretionary resources.

Effect on Public-Facing or State-Supported Programs

38. Our institution operates multiple programs funded jointly by NIH and the State of Maryland, including community health clinics and research addressing health disparities.

39. Grant terminations lead to diminished access to healthcare including to individuals at risk of HIV and those from groups with documented disparities in health outcomes. For example, one terminated grant examined the benefits of client-centered care coordination in uptake and adherence to pre-exposure prophylaxis (PrEP) to prevent the spread of HIV. PrEP use reduces the risk of acquiring an HIV infection by 92%, but only about 19% of the targeted population used PrEP in 2019. Interventions that increase PrEP adherence in key populations can save many lives.

Admissions, Training and Workforce Disruptions

40. UMB uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level. Most doctoral students in the biomedical sciences are supported (tuition and living stipend) through NIH grants, due to the highly specialized and advanced nature of their education. Ph.D. students play a critical role in research - not only for current research projects but also receive training to take on the most pressing scientific questions of the future. A loss of Ph.D. training will lead to a loss in scientific discoveries and will ultimately degrade human health.

41. UMB has had to reduce its incoming class of graduate students due to uncertainty over incoming grant funding because of the delays in reviewing and awarding grants by NIH. For example, UMB's School of Pharmacy decreased its offers by 30%.

42. Similar to private industries, a stable and predictable infrastructure for biomedical research encourages long-term investments and commitments that enable major leaps forward in our understanding of human health and well-being. Earning a Ph.D. in the biomedical sciences is typically a 5- to 7-year commitment by the student and the university. Disruptions to this infrastructure drive talented and promising individuals out of biomedical research, depleting American competitiveness and economic growth.

43. NIH training and research education grants, including T32, R25, and F31 mechanisms, have been affected by review and award delays or changed deadlines. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support postbaccalaureate research education activities that complement and/or enhance the training of a workforce to meet the nation's biomedical, behavioral and clinical research needs (R25), and predoctoral dissertation research (F31 grants).

44. For example, the R25 NOFO (PAR-22-220) was suddenly closed a day before the deadline, which meant UMB could not submit its renewal application despite UMB receiving funding related to this program since 2016.

45. We have international postdocs whose visa status is now at risk due to pending NIH awards that were expected to be renewed this spring.

46. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the

research capabilities of UMB, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

47. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

48. Several major proposals from our institution remain stalled at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

49. Our principal investigators and research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

50. The delays have disrupted ongoing research. Funding gaps have forced researchers to abandon projects, miss deadlines, or lose key personnel.

51. Some of the studies for which UMB has suffered delays, including studies which are in limbo having already received fundable scores and advisory council review, involve clinical trials for life-saving medications or procedures. These delays harm lives of patients. For example, one is a trial involving assisted living residents with Alzheimer's disease and related dementias. Another relates to prescribing the best antidiabetic drug for each person (i.e. using genetics to determine who will respond best to different classes of drugs).

52. One terminated grant funded a study involving more than 1000 human subjects who underwent diagnostic tests as part of the funded study. The human subjects consented to the study based on the understanding that they would be provided with test results that could be important

to their health. The abrupt termination of the grant takes away federal funding for providing subjects with those test results.

53. Some of the studies for which UMB has received terminations involve use of animal subjects, which would need to be euthanized due to loss of funding.

54. Some of these studies had the potential to achieve significant breakthroughs which would have advanced public health, and which will now not occur.

55. Delays have also disrupted community services, student opportunities, and public programs.

56. In most cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

57. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 2nd day of April, 2025, in Baltimore, Maryland.

Bruce E Jarrell

Dr. Bruce E. Jarrell, M.D., FACS
President
University of Maryland, Baltimore

EXHIBIT 1

National Institutes of Health
Office of Extramural Research

March 11, 2025

Christine R. Toalepai
Authorized Organizational Official
University of Maryland Baltimore
220 Arch Street, Ofc Level 2
Baltimore, MD 21201
Redacted

Dear Christine R. Toalepai:

Funding for Project Number 3R01MD019029-02S1 (supplement) is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 25, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 3R01MD019029-02S1 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls on behalf of Priscilla Grant

Director, Office of Policy for Extramural Research Administration, OER

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT 2



03/20/2025

Kenneth Fahnestock
UNIVERSITY OF MARYLAND BALTIMORE
Redacted

Dear Kenneth Fahnestock:

Effective with the date of this letter, funding for Project Number 5R01HL165686-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Anthony Agresti, Chief Grants Management Officer, National Heart, Lung, and Blood Institute
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 3

National Institutes of Health
Office of Extramural Research

3/21/2025

Gregory J Sorensen
University Of Maryland Baltimore
Redacted

Dear Gregory J Sorensen:

Effective with the date of this letter, funding for Project Number 5D43TW012274-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to *SAspending.gov.*

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Bruce Butrum, Chief Grants Management Officer, FIC

[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

EXHIBIT 4

Department of Health and Human Services
National Institutes of Health
FOGARTY INTERNATIONAL CENTER

Notice of Award
FAIN# D43TW012274
Federal Award Date
03/22/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF MARYLAND, BALTIMORE
220 ARCH ST OFC LEVEL2
BALTIMORE, MD 21201

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1526002036A1

4. Employer Identification Number (EIN)
526002036

5. Data Universal Numbering System (DUNS)
188435911

6. Recipient's Unique Entity Identifier
Z9CRZKD42ZT1

7. Project Director or Principal Investigator
Manhattan E Charurat, PHD (Contact)
Professor
Redacted
Redacted

8. Authorized Official
KENNETH E FAHNESTOCK
Redacted
Redacted

Federal Agency Information

9. Awarding Agency Contact Information
SATABDI RAYCHOWDHURY
Grants Management Specialist
FOGARTY INTERNATIONAL CENTER
satabdi.raychowdhury@nih.gov
301-496-9750

10. Program Official Contact Information
Flora N Katz
Program
FOGARTY INTERNATIONAL CENTER
flora.katz@nih.gov
301-402-9591

Federal Award Information

11. Award Number
3D43TW012274-03S1

12. Unique Federal Award Identification Number (FAIN)
D43TW012274

13. Statutory Authority
42 USC 287b 42 CFR 63a

14. Federal Award Project Title
INSIGHT Supplement June 2024

15. Assistance Listing Number
93.989

16. Assistance Listing Program Title
International Research and Research Training

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/02/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$160,746
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$160,746
26. Project Period Start Date 07/02/2024 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,563,052

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
BRUCE R BUTRUM

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

International Research Training Award
Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

SECTION I – AWARD DATA – 3D43TW012274-03S1 REVISED

Principal Investigator(s):
Manhattan E Charurat (contact), PHD
ANNA M MANDALAKAS, MD
Vishwajit Laxmikant Nimgaonkar, MD
Janet M Turan, PHD

Award e-mailed to: Redacted

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MARYLAND BALTIMORE in support of the above referenced project. This award is pursuant to the authority of 42 USC 287b 42 CFR 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number D43TW012274. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

BRUCE R BUTRUM
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Training related Expenses	$31,118

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Participant Other	$124,470
Federal Direct Costs	$155,588
Federal F&A Costs	$5,158
Approved Budget	$160,746
Total Amount of Federal Funds Authorized (Federal Share)	$160,746
TOTAL FEDERAL AWARD AMOUNT	$160,746
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3D43TW012274-03S1	$160,746
5D43TW012274-03	$1,036,244
3D43TW012274-03S2	$100,000
3D43TW012274-03S3	$75,000
TOTAL	**$1,371,990**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$160,746	$1,371,990

Fiscal Information:
Payment System Identifier: 1526002036A1
Document Number: DTW012274A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8027143	$80,373
OD	8055783	$80,373

NIH Administrative Data:
PCC: GLBLFELO / **OC**: 41012 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:12:03 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3D43TW012274-03S1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 3D43TW012274-03S1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) D43TW012274. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – TW SPECIFIC AWARD CONDITIONS – 3D43TW012274-03S1 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Grant Termination
It is the policy of NIH not to prioritize Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are

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often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Therefore, this project is terminated. UNIVERSITY OF MARYLAND BALTIMORE may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

This revision is made per the letter dated March 21, 2025 and supersedes the Notice of Award, (NoA) issued: 08/27/2024

****

REVISED SUPPLEMENT TERM

This supplement provides a total award amount of $80,373 (ORWH) co-funding and a total award amount of $80,373 (OAR) co-funding.

This supplement provides **$160,746** (total cost) of co-funding from The Office of Research on Women's Health (ORWH) in support of one trainees (Serah Gitome **$80,373**) working in Kenya and The Office of AIDS Research (OAR) in support of one trainees (Dr.Samuel Mwaniki **$80,373**) working at Kenya. Any change in the use of these funds requires FIC prior approval.

SUPPLEMENT PROGRESS REPORT

The progress report for the parent award must include separate progress update(s) for each supplement (including this one).

ACKNOWLEDGEMENT OF FUNDING

Each publication, press release, or other document about research supported by an NIH award must include acknowledgment of FIC and ORWH, OAR and NIH award support with the following or comparable footnote and disclaimer:

Research reported in this publication was supported by the Fogarty International Center and The Office of Research on Women's Health (ORWH) and The Office of AIDS Research (OAR) of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

This publication requirement applies not only to the primary grantee, but also to any subcontractors and /or trainees involved with the project.

For additional information, please visit http://www.nih.gov/about/publicaccess/.

HUMAN SUBJECT AND ANIMAL RESEARCH INFORMATION FOR TRAINING GRANTS – DELAYED ONSET

FIC funded research must have the appropriate required NIH and HHS assurances before any research or research training involving human subjects begins. These assurances apply to all research grants, any

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research supported by training grants (including re-entry support for foreign scientists), and research supported under a cooperative agreement. All human subjects research projects must have had a scientific review either by a peer review panel or by another independent review mechanism. Activity in which human subjects are involved may be undertaken if the institution has an active FWA assurance and if the project has been reviewed and approved by the appropriate Institutional Review Board (IRB).

Grant recipients must provide human subjects and IRB approval information in Section G.1 "Special NOA terms and FOA reporting requirements" of the RPPR for each trainee/scholar supported by the grant award during the reporting period. Additional information on this requirement can be found in the FIC Progress Report Supplemental Guidance on the FIC webpage: http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx.

FOREIGN TRAVEL
U.S. Flag carriers must be used for departure from or entry into the U.S. and for other portions of the trip where available. Please see the link for questions regarding Foreign Travel.
https://www.fic.nih.gov/Grants/Pages/Foreign-Travel.aspx

UNIFORM GRANT GUIDANCE AND REVISED NIH GRANTS POLICY STATEMENT
Per Notice Number NOT-OD-15-046, the Department of Health and Human Services published an interim rule adapting OMB's final Uniform Grant Guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department effective December 26, 2014. The current revised NIH Grants Policy Statement is applicable to all NIH grants and cooperative agreements.
Information regarding the NIH Grants Policy Statement can be found at: https://grants.nih.gov/policy/index.htm
Highlighted below are some select items of costs of particular note to FIC grant recipients:

- F&A for Foreign and International Organizations: NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of equipment, tuition and related fees, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. This applies to direct foreign awards and foreign subawards.
- F&A for Career/Fellowship/Training Awards: NIH and FIC continue to provide F&A costs under research training, some education grants, and Career (K) awards will be funded at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), equipment, and consortiums in excess of $25,000, consistent with existing policy.
- Value Added Tax: Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
- Visa Costs: Visa costs may be allowable when identified in specific FOAs or when within the scope of an approved research project. Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual.

ALL OTHER TERMS AND CONDITIONS OF THIS PROGRAM AS NOTED IN THE FUNDING ANNOUNCEMENT, THE PARENT AWARD TERMS, AND THE NIH GRANTS POLICY STATEMENT ARE HEREBY INCORPORATED INTO THE TERMS OF THIS SUPPLEMENT.

SPREADSHEET SUMMARY
AWARD NUMBER: 3D43TW012274-03S1 REVISED

INSTITUTION: UNIVERSITY OF MARYLAND BALTIMORE

Budget	Year 3
Training related Expenses	$31,118
Participant Other	$124,470
TOTAL FEDERAL DC	$155,588
TOTAL FEDERAL F&A	$5,158

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TOTAL COST	$160,746

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	8%
F&A Cost Base 1	$64,475
F&A Costs 1	$5,158

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EXHIBIT 5

Department of Health and Human Services
National Institutes of Health
FOGARTY INTERNATIONAL CENTER

Notice of Award
FAIN# D43TW012274
Federal Award Date
03/23/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF MARYLAND, BALTIMORE
220 ARCH ST OFC LEVEL2
BALTIMORE, MD 21201

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1526002036A1

4. Employer Identification Number (EIN)
526002036

5. Data Universal Numbering System (DUNS)
188435911

6. Recipient's Unique Entity Identifier
Z9CRZKD42ZT1

7. Project Director or Principal Investigator
Manhattan E Charurat, PHD (Contact)
Professor
Redacted
Redacted

8. Authorized Official
KENNETH E FAHNESTOCK
Redacted
Redacted

Federal Agency Information

9. Awarding Agency Contact Information
SATABDI RAYCHOWDHURY
Grants Management Specialist
FOGARTY INTERNATIONAL CENTER
satabdi.raychowdhury@nih.gov
301-496-9750

10. Program Official Contact Information
Flora N Katz
Program
FOGARTY INTERNATIONAL CENTER
flora.katz@nih.gov
301-402-9591

Federal Award Information

11. Award Number
3D43TW012274-03S2

12. Unique Federal Award Identification Number (FAIN)
D43TW012274

13. Statutory Authority
42 USC 287b 42 CFR 63a

14. Federal Award Project Title
INSIGHT Supplement (ODP) July 2024

15. Assistance Listing Number
93.989

16. Assistance Listing Program Title
International Research and Research Training

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/15/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$100,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$100,000
26. Project Period Start Date 08/15/2024 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,563,052

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
BRUCE R BUTRUM

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

International Research Training Award
Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

SECTION I – AWARD DATA – 3D43TW012274-03S2 REVISED

Principal Investigator(s):
Manhattan E Charurat (contact), PHD
ANNA M MANDALAKAS, MD
Vishwajit Laxmikant Nimgaonkar, MD
Janet M Turan, PHD

Award e-mailed to: Redacted

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MARYLAND BALTIMORE in support of the above referenced project. This award is pursuant to the authority of 42 USC 287b 42 CFR 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number D43TW012274. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

BRUCE R BUTRUM
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Other	$37,037

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Stipends	$60,000
Federal Direct Costs	$97,037
Federal F&A Costs	$2,963
Approved Budget	$100,000
Total Amount of Federal Funds Authorized (Federal Share)	$100,000
TOTAL FEDERAL AWARD AMOUNT	$100,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3D43TW012274-03S2	$100,000
5D43TW012274-03	$1,036,244
3D43TW012274-03S1	$160,746
3D43TW012274-03S3	$75,000
TOTAL	**$1,371,990**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$100,000	$1,371,990

Fiscal Information:
Payment System Identifier: 1526002036A1
Document Number: DTW012274A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8010093	$100,000

NIH Administrative Data:
PCC: GLBLFELO / **OC**: 41012 / **Released**: 03/21/2025
Award Processed: 03/23/2025 12:00:39 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3D43TW012274-03S2 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 3D43TW012274-03S2 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

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awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) D43TW012274. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted

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electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – TW SPECIFIC AWARD CONDITIONS – 3D43TW012274-03S2 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Grant Termination
It is the policy of NIH not to prioritize Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research

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programs. Therefore, this project is terminated. UNIVERSITY OF MARYLAND BALTIMORE may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

This revision is made per the letter dated March 21, 2025 and supersedes the Notice of Award, (NoA) issued: 08/19/2024

****

SUPPLEMENT TERM

This supplement provides a total award amount of $100,000 ODP co-funding.

This supplement provides $100,000 (total cost) of co-funding from The Office of Disease Prevention (ODP) in support of two trainees (Dr. Sujata Sapkota and Dr. Josephine Tumuhamye) working in Nepal and Uganda. Any change in the use of these funds requires FIC prior approval.

SUPPLEMENT PROGRESS REPORT

The progress report for the parent award must include separate progress update(s) for this supplement.

ACKNOWLEDGEMENT OF FUNDING

Each publication, press release, or other document about research supported by an NIH award must include acknowledgment of FIC and ODP and NIH award support with the following or comparable footnote and disclaimer:

Research reported in this publication was supported by the Fogarty International Center and The Office of Disease Prevention (ODP) of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

This publication requirement applies not only to the primary grantee, but also to any subcontractors and /or trainees involved with the project.

For additional information, please visit http://www.nih.gov/about/publicaccess/.

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Grant recipients must provide human subjects and IRB approval information in Section G.1 "Special NOA terms and FOA reporting requirements" of the RPPR for each trainee/scholar supported by the grant award during the reporting period. Additional information on this requirement can be found in the FIC Progress Report Supplemental Guidance on the FIC webpage: http://www.fic.nih.gov/Grants/Pages/progress-reports.aspx.

FOREIGN TRAVEL

U.S. Flag carriers must be used for departure from or entry into the U.S. and for other portions of the trip where available. Please see the link for questions regarding Foreign Travel.

https://www.fic.nih.gov/Grants/Pages/Foreign-Travel.aspx

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UNIFORM GRANT GUIDANCE AND REVISED NIH GRANTS POLICY STATEMENT

Per Notice Number NOT-OD-15-046, the Department of Health and Human Services published an interim rule adapting OMB's final Uniform Grant Guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department effective December 26, 2014. The current revised NIH Grants Policy Statement is applicable to all NIH grants and cooperative agreements.

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Highlighted below are some select items of costs of particular note to FIC grant recipients:

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- F&A for Career/Fellowship/Training Awards: NIH and FIC continue to provide F&A costs under research training, some education grants, and Career (K) awards will be funded at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), equipment, and consortiums in excess of $25,000, consistent with existing policy.
- Value Added Tax: Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
- Visa Costs: Visa costs may be allowable when identified in specific FOAs or when within the scope of an approved research project. Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual.

ALL OTHER TERMS AND CONDITIONS OF THIS PROGRAM AS NOTED IN THE FUNDING ANNOUNCEMENT, THE PARENT AWARD TERMS, AND THE NIH GRANTS POLICY STATEMENT ARE HEREBY INCORPORATED INTO THE TERMS OF THIS SUPPLEMENT.

SPREADSHEET SUMMARY
AWARD NUMBER: 3D43TW012274-03S2 REVISED

INSTITUTION: UNIVERSITY OF MARYLAND BALTIMORE

Budget	Year 3
Other	$37,037
Stipends	$60,000
TOTAL FEDERAL DC	$97,037
TOTAL FEDERAL F&A	$2,963
TOTAL COST	$100,000

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	8%
F&A Cost Base 1	$37,037
F&A Costs 1	$2,963

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EXHIBIT 6

Department of Health and Human Services
National Institutes of Health
FOGARTY INTERNATIONAL CENTER

Notice of Award
FAIN# D43TW012274
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF MARYLAND, BALTIMORE
220 ARCH ST OFC LEVEL2
BALTIMORE, MD 21201

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1526002036A1

4. Employer Identification Number (EIN)
526002036

5. Data Universal Numbering System (DUNS)
188435911

6. Recipient's Unique Entity Identifier
Z9CRZKD42ZT1

7. Project Director or Principal Investigator
Manhattan E Charurat, PHD (Contact)
Professor
Redacted
Redacted

8. Authorized Official
KENNETH E FAHNESTOCK
Redacted
Redacted

Federal Agency Information

9. Awarding Agency Contact Information
SATABDI RAYCHOWDHURY
Grants Management Specialist
FOGARTY INTERNATIONAL CENTER
satabdi.raychowdhury@nih.gov
301-496-9750

10. Program Official Contact Information
Flora N Katz
Program
FOGARTY INTERNATIONAL CENTER
flora.katz@nih.gov
301-402-9591

Federal Award Information

11. Award Number
3D43TW012274-03S3

12. Unique Federal Award Identification Number (FAIN)
D43TW012274

13. Statutory Authority
42 USC 287b 42 CFR 63a

14. Federal Award Project Title
Supplement_INSIGHT_Orientation

15. Assistance Listing Number
93.989

16. Assistance Listing Program Title
International Research and Research Training

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/30/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$75,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$75,000
26. Project Period Start Date 08/30/2024 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,563,052

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
BRUCE R BUTRUM

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

International Research Training Award
Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

SECTION I – AWARD DATA – 3D43TW012274-03S3 REVISED

Principal Investigator(s):
Manhattan E Charurat (contact), PHD
ANNA M MANDALAKAS, MD
Vishwajit Laxmikant Nimgaonkar, MD
Janet M Turan, PHD

Award e-mailed to: Redacted

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MARYLAND BALTIMORE in support of the above referenced project. This award is pursuant to the authority of 42 USC 287b 42 CFR 63a and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under Award Number D43TW012274. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

BRUCE R BUTRUM
Grants Management Officer
FOGARTY INTERNATIONAL CENTER

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Other	$69,444

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Federal Direct Costs	$69,444
Federal F&A Costs	$5,556
Approved Budget	$75,000
Total Amount of Federal Funds Authorized (Federal Share)	$75,000
TOTAL FEDERAL AWARD AMOUNT	$75,000

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3D43TW012274-03S3	$75,000
5D43TW012274-03	$1,036,244
3D43TW012274-03S1	$160,746
3D43TW012274-03S2	$100,000
TOTAL	**$1,371,990**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$75,000	$1,371,990

Fiscal Information:
Payment System Identifier: 1526002036A1
Document Number: DTW012274A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
TW	8476367	$75,000

NIH Administrative Data:
PCC: GLBLFELO / **OC**: 41012 / **Released**: 03/21/2025
Award Processed: 03/24/2025 12:08:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3D43TW012274-03S3 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 3D43TW012274-03S3 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor

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should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) D43TW012274. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted

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electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – TW SPECIFIC AWARD CONDITIONS – 3D43TW012274-03S3 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Grant Termination
It is the policy of NIH not to prioritize Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Therefore, this project is terminated. UNIVERSITY OF MARYLAND BALTIMORE may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance

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Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

This revision is made per the letter dated March 21, 2025 and supersedes the Notice of Award, (NoA) issued: 09/05/2024

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AWARD FOR ORIENTATION SUPPLEMENT

This supplement provides $75,000 (total cost), as requested, in support to the Global Health Program for Fellows and Scholars LAUNCH 2025 Orientation Activities for the seven Support Centers (UNC, UMD, UW, Harvard, UCSF, Yale and WU in St. Louis) held on NIH campus or Virtual. Any change in the use of these funds requires FIC prior approval. These funds can not be used for Honoria costs.

SUPPLEMENT PROGRESS REPORT

The progress report for the parent award must include separate progress update(s) for this supplement.

ACKNOWLEDGEMENT OF FUNDING

Each publication, press release, or other document about research supported by an NIH award must include acknowledgment of FIC and NIH award support with the following or comparable footnote and disclaimer:
Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.
Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.
This publication requirement applies not only to the primary grantee, but also to any subcontractors and /or trainees involved with the project.
For additional information, please visit http://www.nih.gov/about/publicaccess/.

UNIFORM GRANT GUIDANCE AND REVISED NIH GRANTS POLICY STATEMENT

Per Notice Number NOT-OD-15-046, the Department of Health and Human Services published an interim rule adapting OMB's final Uniform Grant Guidance in 2 CFR part 200 with certain amendments, based on existing HHS regulations, to supplement the guidance as needed for the Department effective December 26, 2014. The current revised NIH Grants Policy Statement is applicable to all NIH grants and cooperative agreements.
Information regarding the NIH Grants Policy Statement can be found at: https://grants.nih.gov/policy/index.htm
Highlighted below are some select items of costs of particular note to FIC grant recipients:

- F&A for Foreign and International Organizations: NIH and FIC continue to provide F&A costs under grants to foreign and international organizations will be funded at a rate of 8 percent of modified total direct costs, exclusive of equipment, tuition and related fees, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. This applies to direct foreign awards and foreign subawards.
- F&A for Career/Fellowship/Training Awards: NIH and FIC continue to provide F&A costs under research training, some education grants, and Career (K) awards will be funded at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, health insurance (when awarded as part of tuition and fees), equipment, and consortiums in excess of $25,000, consistent with existing policy.
- Value Added Tax: Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. However, for many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.

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- Visa Costs: Visa costs may be allowable when identified in specific FOAs or when within the scope of an approved research project. Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual.

ALL OTHER TERMS AND CONDITIONS OF THIS PROGRAM AS NOTED IN THE FUNDING ANNOUNCEMENT, THE PARENT AWARD TERMS, AND THE NIH GRANTS POLICY STATEMENT ARE HEREBY INCORPORATED INTO THE TERMS OF THIS SUPPLEMENT.

SPREADSHEET SUMMARY
AWARD NUMBER: 3D43TW012274-03S3 REVISED

INSTITUTION: UNIVERSITY OF MARYLAND BALTIMORE

Budget	Year 3
Other	$69,444
TOTAL FEDERAL DC	$69,444
TOTAL FEDERAL F&A	$5,556
TOTAL COST	$75,000

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	8%
F&A Cost Base 1	$69,444
F&A Costs 1	$5,556

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EXHIBIT 7



03/20/2025

Gregory Sorensen
UNIVERSITY OF MARYLAND BALTIMORE
Redacted

Dear Gregory Sorensen:

Effective with the date of this letter, funding for Project Number 5R01DE032225-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 09/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 13:32:12 -04'00'

Michelle G. Bulls, on behalf Gabriel Hidalgo, Chief Grants Management Officer, National Institute of Dental and Craniofacial Research
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 8

Subject: Grant Termination Notification
Date: Friday, March 21, 2025 at 12:30:58 PM Eastern Daylight Time
From: Bulls, Michelle G. (NIH/OD) [E]
To: Redacted
Attachments: image001.jpg, image002.png

You don't often get email from michelle.bulls@nih.gov. Learn why this is important

CAUTION: This message originated from a non-UMB email system. Hover over any links before clicking and use caution opening attachments.





3/21/2025

Christine R. Toalepai
University Of Maryland Baltimore
Redacted

Dear Christine R. Toalepai:

Effective with the date of this letter, funding for Project Number 5R01MH134721-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful

discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.***[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 9

Subject: Grant Termination Notification
Date: Friday, March 21, 2025 at 12:30:33 PM Eastern Daylight Time
From: Bulls, Michelle G. (NIH/OD) [E]
To: Redacted
Attachments: image001.jpg, image002.png

You don't often get email from michelle.bulls@nih.gov. Learn why this is important

CAUTION: This message originated from a non-UMB email system. Hover over any links before clicking and use caution opening attachments.





3/21/2025

Toalepai, Christine R.
University Of Maryland Baltimore
Redacted

Dear Toalepai, Christine R.:

Effective with the date of this letter, funding for Project Number 5R01MD019029-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 4/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful

discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.***[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 10

Subject: Fwd: Grant Termination Notification
Date: Friday, March 21, 2025 at 12:59:47 PM Eastern Daylight Time
From: Sorensen, Gregory J.
To: Frankenfield, Jill
Attachments: image001.jpg, image002.png

Here is another one

Greg J. Sorensen
Assistant Director, Sponsored Programs Admin.
Office of Research and Development
University of Maryland, Baltimore
620 W. Lexington Street, 4th Floor
Baltimore, Maryland 21201
Redacted

Email: Redacted
(AWS Every other Monday, work hours 7am to 4pm)

Begin forwarded message:

From: "Bulls, Michelle G. (NIH/OD) [E]" <michelle.bulls@nih.gov>
Subject: Grant Termination Notification
Date: March 21, 2025 at 12:30:12 PM EDT
To: "Redacted

You don't often get email from michelle.bulls@nih.gov. Learn why this is important
CAUTION: This message originated from a non-UMB email system. Hover over any links before clicking and use caution opening attachments.

National Institutes of Health
Office of Extramural Research

3/21/2025

Gregory J. Sorensen
University Of Maryland Baltimore
Redacted

Dear Gregory J. Sorensen:

Effective with the date of this letter, funding for Project Number 5UG1HD113162-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10] You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11] The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 11

Scripps Research

March 27, 2025

SPA Contracts
University of Maryland, Baltimore
620 West Lexington St. 4th Floor
Baltimore, MD 21201-1508
Redacted

Re: Termination of Subaward No. 5-54820 under NIH Award No. 1U19AI171443-01

Dear SPA Contracts:

This letter serves as formal notice that The Scripps Research Institute ("Scripps") is terminating Subaward No. 5-54820 issued to University of Maryland, Baltimore ("Subrecipient") pursuant to Paragraph 9 of the Subaward Agreement and in accordance with 2 C.F.R. § 200.340(a)(4). This action follows the termination of the NIH Prime Award No. 1U19AI171443-01, effective March 24, 2025.

The National Institutes of Health ("NIH") terminated the prime award pursuant to the Fiscal Year 2022 NIH Grants Policy Statement and 2 C.F.R. § 200.340(a)(4), which permits a federal awarding agency to terminate an award when it no longer effectuates program goals or agency priorities.

Because the Subaward is contingent upon the continued availability of funds under the prime award, and because the terms of the Subaward explicitly incorporate this dependency, your Subaward is likewise subject to termination. This decision is made without consideration of fault or deficiency on your part. To the extent that you have not already, please immediately cease and cancel any and all work or services associated with your performance of the Subaward.

In accordance with 2 C.F.R. § 200.344 and other applicable provisions of the Uniform Guidance, we request that your institution undertake the following actions to complete the closeout process:

1. Submit a final invoice reflecting allowable costs incurred through the effective date of termination. Costs incurred after March 24, 2025 are not allowable and may not be claimed. The final invoice must be submitted no later than 60 calendar days from the date of this letter.

2. Ensure all costs are consistent with the principles of allowability, allocability, reasonableness, and consistency as defined in 2 C.F.R. Part 200 Subpart E.

3. Submit any required final technical reports, invention disclosures, or property disposition reports as may be applicable under the Subaward Agreement and incorporated federal requirements.

4. Ensure that all financial and performance obligations are concluded to allow for full compliance with 2 C.F.R. §§ 200.344–200.345.

Please direct invoices and closeout documentation to ospinvoices@scripps.edu.

Scripps acknowledges and appreciates the substantial efforts and contributions your team made in support of this important work. While it is unfortunate that the prime award has been terminated prematurely due to changes in federal research priorities, we thank you for your professionalism and collaboration throughout the term of the project.

Sincerely,

DocuSigned by:
Tommy R. Rice
89E9BA601DE7486...

Tommy R. Rice
Cost Compliance Officer
The Scripps Research Institute
CC: Redacted

EXHIBIT 20

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF JOHN J. FARMER, JR.

I, John J. Farmer, Jr., upon information and belief, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the following is true and correct:

1. I am the Interim Senior Vice President and General Counsel of Rutgers, the State University of New Jersey.

2. I have compiled the information in the statements set forth below through review of Rutgers's records and other documents gathered by Rutgers personnel who have assisted me and on the basis of documents that have been provided to and/or reviewed by me in order to understand their immediate impact on Rutgers.

3. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

A. Professional Background

4. I am the Interim Senior Vice President and General Counsel at Rutgers, the State University of New Jersey. I have served in this capacity since 2024. I am the chief counsel for the

university. Previously, I have served as Dean of Rutgers School of Law-Rutgers and Director of the Eagleton Institute. From 1999-2002 I was Attorney General of the State of New Jersey.

5. Founded in 1766, Rutgers is the oldest, largest, and highest-ranked public university in the New York/New Jersey Metropolitan area and is among the nation's highest-ranked public research universities.

6. As New Jersey's land-grant university, Rutgers has a significant academic and clinical health sciences presence across the state, including activity in each of the State's 21 counties and three campuses located in the cities of Camden, Newark, and New Brunswick, New Jersey.

7. Rutgers is accredited as one university, and the president presides over the University as the chief executive officer. Reporting to the president are four chancellors: the Chancellors of Rutgers University–New Brunswick and Rutgers Health—whose units together compose the Association of American Universities (AAU) unit of Rutgers—and the chancellors of Rutgers University–Newark and Rutgers University–Camden.

8. Within this four-unit structure are numerous research centers and institutes, academic medical centers, and 29 schools and colleges, including colleges of liberal arts and sciences, a school of environmental and biological sciences, a school of engineering, a school of the arts, other professional schools, and graduate programs. Rutgers presently serves over 69,000 students, 82% of whom are New Jersey residents.

9. As one of the largest employers in the state, Rutgers has a workforce that includes more than 10,000 full- and part-time faculty members and more than 17,450 full- and part-time staff.

10. Each of the Rutgers units has its own distinct characteristics that contribute to the strength of our university; all are recognized within the U.S. News & World Report: America's Best Colleges top 50 public, national universities.

11. Rutgers–New Brunswick, established in 1766, is New Jersey's leading public research university—a Research 1 designated institution and our largest chancellor-led unit.

12. Rutgers–Newark, is an urban research (R2) university located in New Jersey's largest city that leverages its diversity and proximity to New York City. It is recognized as a driver of economic prosperity and social mobility and an anchor institution for its host city of Newark.

13. Rutgers–Camden, our southern-most and smallest campus, is located in the Delaware Valley, which affords its community access not just to a personalized, close-knit, and robust experience on campus but also to the academic, cultural, and career resources available just across the Delaware River in Philadelphia.

14. The University's fourth chancellor-led unit, Rutgers Health, is one of the nation's largest academic health centers, integrating education, research, and clinical care. It is also the largest academic health center within the state. Rutgers Health offers the broadest scope of programs for educating doctors, nurses, dentists, pharmacists, and other healthcare professionals in medicine, nursing, dentistry, pharmacy, and other health professions, making it a leading institution for healthcare education in New Jersey. It is home to Rutgers Cancer Institute of New Jersey, the State of New Jersey's only National Cancer Institute-designated Comprehensive Cancer Center.

15. In addition to providing higher education to students from New Jersey and across the nation, Rutgers also supports significant medical and behavioral research and clinical trials

across its colleges and schools. Rutgers conducts vital research across a wide range of areas including heart disease, cancer, neuroscience and brain health, and infectious disease.

16. To fund these crucial medical research programs, Rutgers is the recipient of federal funding, including annual funding from NIH in the total amount of approximately $250 million. NIH funding at Rutgers currently supports nearly 1,200 separate grants and more than 2,200 employees.

B. Reliance on NIH Funding

17. In fiscal year 2024, Rutgers received funding through the National Institutes of Health ("NIH") to support approximately 1,200 projects, totaling approximately $250 million.

18. Rutgers receives NIH grants across a variety of institutes encompassed within the NIH**,** including but not limited to the National Institutes on Aging, National Institute on Minority Health and Health Disparities, and National Heart Lung and Blood Institute.

19. Through those NIH grants, Rutgers funds over 2,400 faculty and staff positions in whole or in part.

20. Rutgers provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New Jersey economy.

C. Terminations of NIH Grants

21. Since January 20th, 2025, Rutgers has had four NIH grants terminated.

22. The terminations received through March 31, 2025, are attached hereto as Exhibits A, C, E, and G.

23. These terminations will result in a prospective loss of $4,580,826 across the remaining grants years associated with these grants.

24. The four NIH grants currently support, in whole or in part, the personnel expenses of 20 faculty and staff members.

25. These terminations have triggered a loss of $1,966,042.44 across the four grants for the current budgetary period as discussed in more detail below, subject to the final close out process.

26. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities."

27. The termination notices have also stated that there is "no corrective action" that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, Rutgers had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities despite policy guidance from NIH that "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision." 2024 NIH Grants Policy Statement at IIA-156. Nor was Rutgers provided with any updated "agency priorities" with which its research must align.

Social Networks and Cognitive Health Among Black and Latino Sexual Minority Men in NJ (NIH Project Number 1R01AG089099)

28. NIH terminated grant funding for a study by Rutgers School of Public Health researchers of the social networks and cognitive health among Black and Latino sexual minority men in New Jersey, Project Number 1R01AG089099-01 on March 11, 2025. The Notice of Award ("NOA") for this grant is attached as Exhibit B. This study sought to understand how interpersonal processes and social network characteristics affect health behaviors related to cognitive performance. The study aimed to assess how social networks in the sample population are constructed and how social and physical activities in those networks may be protective for

cognitive performance. The project period for this grant spans from September 23, 2024 to August 31, 2029.

29. This grant was approved in response to a Notice of Funding Opportunity, RFA-AG-24-025, from the National Institute on Aging made available on June 8, 2023.

30. The National Institute on Aging's leads a national program of research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities; and the promotion of a better quality of life for all older Americans.

31. The grant was for a five-year period and awarded on September 20, 2024. This funding was intended to pay research faculty and staff, the preparation and distribution of materials, and other incidental research costs associated with the study. Five faculty members and two staff members are affiliated with the project.

32. The first budget period for this grant covered September 23, 2024 to August 31, 2025. At the time of termination, the total amount spent in this first budget period was $270,020, while the total amount awarded for this timeframe was $739,827. Therefore, for this period of time, the total funding lost upon the grant's termination was $469,807, subject to the final close out and adjustment process. The total estimated future loss due to termination is $2,833,758. This estimated loss includes the full grant award of $702,062 in 2026, $708,670 in 2027, and $711,412 in 2028. The project was scheduled to end on August 31, 2029. The reason for termination was that "programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." *See* Exhibit A. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

33. This project includes a community advisory board, who were integral in the development of the community-engagement portions of the study. Loss of funding would mean that the study fails to fulfill its agreed-upon expectations, meetings, and engagement with the community advisory board. This has the potential to damage trust between the academic institution and critical community partners, undermining years of relationship building. Participants who required any diagnostic assessments will no longer be able to receive those assessments.

34. This award also includes funds awarded for consortium activity with the University of Pittsburgh in the amount of $44,504 and NJ Community Research Initiative ("NJCRI") in the amount of $115,842. Seven faculty and five staff members are affiliated with subcontracted consortium activities. Consortiums are established and administered as described in the NIH Grants Policy Statement.

Stigma and the Non-Communicable Disease Syndemic in Aging HIV Positive and HIV Negative MSM (NIH Project Number 5R01HL160326-05)}

35. NIH also terminated funding for Rutgers School of Public Health researchers to perform a mixed-methods study of factors associated with HIV prevention among Latino/x migrant men, Project Number 5R01HL160326-05, on March 19, 2025. The NOA for this grant is attached as Exhibit D. This study aimed to address the prevalence of HIV infection among Latino/x sexual minority men by examining how social ecological factors magnify HIV infection risks in this population. The project received its funding from the National Heart, Lung, and Blood Institute in response to a Funding Opportunity Announcement, RFA-HL-21-018.

36. The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives. The NHLBI stimulates basic discoveries about the causes of disease, enables

the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public.

37. This announcement was aimed at identifying strategies that foster holistic approaches in the clinical management of people living with HIV who also have heart, lung, blood, and sleep ("HLBS") comorbidities, and to utilize existing data to assess the feasibility and cost-effectiveness of such approaches. The grant was awarded on February 1, 2023. This funding was intended to pay research faculty and staff, the preparation and distribution of materials, and other incidental research costs associated with the study. One faculty member and one staff member are affiliated with this project.

38. At the time of termination, the total amount spent in the current budget period, which spanned February 1, 2024 until August 31, 2024, was $344,995, and the total budget awarded for this period of time was $497,040. Therefore, in this timeframe, the total funding lost was $152,045, subject to the final close out and adjustment process. The total estimated future loss due to termination is $487,894, which reflects remaining funding awarded under the grant through the projected end date of August 31, 2026. The reason given for termination was that the program was based on "artificial and non-scientific categories, including amorphous equity objectives." See Exhibit C. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

39. The termination of this funding will have significant and immediate consequences for the 1020 study participants who have been receiving resources for the prevention or treatment of HIV and disrupt the continuum of care for a variety of associated co-morbidities. The loss of funding will also require the waste of biospecimens and the termination of electrocardiography

studies for participants. The loss of funding also forecloses future work on interventions in these critical health contexts.

40. This award includes funds awarded for consortium activity with the Georgetown University, Massachusetts General Hospital, Johns Hopkins University, University of Miami, Northwestern University, University of Alabama at Birmingham, The George Washington University, The Regents of the University of California, Los Angeles, University of Mississippi Medical Center, University of Pittsburgh, Hektoen Institute, and Whitman-Walker Institute, Inc. 12 faculty and 9 staff are affiliated with subcontracted consortium activities. Rutgers, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance project, the appropriate expenditures of grant funds by all parties, and all other obligations of the recipient, as specified in the NIH Grants Policy Statement.

Understanding the Role of Structural Oppression for Suicide Risk among Black Sexual and Gender Minority Adolescents and Young Adults (NIH Project Number 5R01MD018679)

41. NIH also terminated the grant funding for a study by Rutgers School of Public Health researchers on the suicide risk of Black sexual and gender minority adolescents and young adults, Project Number 5R01MD018679 on March 20, 2025. The Notice of Award ("NOA") for this grant is attached as Exhibit F. This study aimed to utilize longitudinal research to assess how stigma and systemic racism affect suicidal thoughts and behaviors. The project received its funding from the National Institute on Minority Health and Health Disparities ("NIMHD") in response to a Funding Opportunity Announcement, RFA-MH-22-140, which was aimed at advancing research to better understand risk and resiliency factors for suicide among Black Youth.

42. The mission of NIMHD is to lead scientific research to improve minority health and eliminate health disparities. To accomplish its mission, NIMHD plans, reviews, coordinates, and evaluates all minority health and health disparities research and activities of the National

Institutes of Health; conducts and supports research in minority health and health disparities; promotes and supports the training of a diverse research workforce; translates and disseminates research information; and fosters innovative collaborations and partnerships.

43. The grant was awarded on May 17, 2024 and was intended to fund research faculty and staff, the preparation and distribution of materials, and other incidental research costs associated with the study. Three faculty members and one staff member are affiliated with this project.

44. This grant provided four years of funding and is scheduled to terminate on December 31, 2027. At the time of termination, the total amount spent in the current budget period (May 17, 2024 to December 31, 2024) for this project was $302,860, while the total budget awarded for that time period was $1,131,947. Therefore, the funding lost in 2025 was $829,087, subject to the final close out and adjustment process. The total estimated future loss due to termination is $1,259,174. This includes losses of prospective awards associated with the grant of $633,470 in 2026 and $625,704 in 2027. The reason given for termination was that the program was based on "artificial and non-scientific categories, including amorphous equity objectives." *See* Exhibit E. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

45. The termination of the grant results in a loss of funding for two community-based organizations, the Hetrick-Martin Institute and the Whitman-Walker Institute that provide social support and healthcare resources to LGBTQ+ youth. Four faculty members and three staff engaged in subcontracted grant work through the Whitman-Walker Institute will also be adversely impacted. The loss of funding also impedes the study's ability to provide suicide prevention

resources, including referrals to mental healthcare, crisis response, and social services for youth found to be at risk for suicide.

Development of Dual Inhibitors Targeting the Viral Main Protease and the Host Cathepsin L as SARS-CoV-2 Antivirals (NIH Project Number 5R01AI158775-04)

46. NIH also terminated the grant funding for a study by Rutgers Ernest Mario School of Pharmacy researchers on the development of an antiviral to treat SARS-CoV-2, Project Number 5R01AI158775-04, on March 24, 2025. The Notice of Award ("NOA") for this grant is attached as Exhibit H. The project received its funding from the National Institute of Allergy and Infectious Diseases ("NIAID") in response to a Funding Opportunity Announcement, PAR-20-178, which was aimed at advancing research about SARS-CoV-2 and Coronavirus Disease 2019 ("COVID-19").

47. NIAID research strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.

48. The grant was awarded on January 4, 2022, and was intended to fund the development of potent antivirals against severe acute respiratory syndrome coronavirus 2 (SARS-CoV2). One faculty member and two staff members are affiliated with this project.

49. This grant provided three years of funding totaling $2,142,404 over that period. At the time of termination, the total amount spent for this project was $1,627,301. Therefore, the funding lost in 2025 was $515,103, subject to the final close out and adjustment process. The reason given for termination was that "[The] grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary." See Exhibit G. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

50. This grant award also includes subcontracted funds for Oklahoma State University, University of Arizona, and the University of South Florida.

D. Impacts from NIH Funding Terminations and Delays and Irreparable Harm

51. Due to the delays and funding uncertainty, and seeking alternative sources of funding, Rutgers faculty and researchers may be forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment, and who may also face deportation as a result of a loss of sponsored visas;

c. Stop ongoing experiments, compromising time-sensitive components of the research;

d. Pause community-based partnerships, disrupting services;

e. Delay work on clinical translation, including potential therapeutic development;

52. Students working in these labs who are relying on research conducted there to obtain their PhDs may see delays in their progression and career development.

53. Shared research core facilities may need to lay off staff and close.

54. These delays may cause slowdowns or pauses in hiring new faculty and staff.

E. Comparisons Across Administrations

55. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

56. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

57. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

F. Admissions, Training and Workforce Disruptions

58. Rutgers may reduce the number of undergraduate and graduate students admitted.

59. NIH training grants, including T32 and F31 mechanisms, may be affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

60. The visa status of international postdocs may be at risk visa status due to pending NIH awards that were expected to renew this spring.

G. Irreparable Harm

61. The delays have disrupted and may disrupt ongoing research, as well as setting back Rutgers for research going forward. Funding gaps may force researchers to abandon studies, miss deadlines, or lose key personnel.

62. Impacts to studies involving clinical trials for life-saving medications or procedures, and their closure could endanger the lives of patients.

63. Some of these studies may have the potential to achieve breakthroughs which would have advanced public health, and which may not occur.

64. Delays may also disrupt community services, student opportunities, and public programs.

65. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

66. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Signed by:
John J. Farmer, Jr.
5400300516C24C0...

John J. Farmer, Jr.
Interim Senior Vice President and General Counsel
Rutgers, The State University of New Jersey

Date: 04/02/2025

EXHIBIT A





March 11, 2025

Rutgers Biomedical and Health Sciences
Gregory Werhner
Authorized Organizational Official
65 Bergen St. Suite 1 Neward, NJ 07107
Email: gregory.werhner@rutgers.edu

Dear Greg Werhbner:

Funding for Project Number 1R01AG089099-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 20, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

termination decision,"[6] no corrective action is possible here. The premise of Project Number 1R01AG089099-01 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls on Behalf of Dr. Ken Santora
Office of Policy for Extramural Research Administration
Office of Extramural Research Administraiton

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT B

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG089099
Federal Award Date
09/20/2024

Recipient Information

1. Recipient Name
RUTGERS THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST
STE 1
NEWARK, NJ 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

6. Recipient's Unique Entity Identifier
YVVTQD8CJC79

7. Project Director or Principal Investigator
Cui Yang, PHD (Contact)
Associate Professor
cy360@rutgers.edu
732-235-9754

8. Authorized Official
Gregory Werhner
gregory.werhner@rutgers.edu

Federal Agency Information

9. Awarding Agency Contact Information
KRISTINA MICHELLE Smith

NATIONAL INSTITUTE ON AGING

10. Program Official Contact Information
Melissa S Gerald
Health Science Administrator
NATIONAL INSTITUTE ON AGING
geraldmel@nia.nih.gov
301-402-4156

Federal Award Information

11. Award Number
1R01AG089099-01

12. Unique Federal Award Identification Number (FAIN)
R01AG089099

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Social Networks and Cognitive Health among Black and Latino sexual minority men in NJ

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/23/2024 **– End Date** 08/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$739,827
20 a. Direct Cost Amount	$511,814
20 b. Indirect Cost Amount	$228,013
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$739,827
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$739,827
26. Project Period Start Date 09/23/2024 **– End Date** 08/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$739,827

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Philip E. Smith

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG089099-01

Principal Investigator(s):
Mackey R Friedman, PHD
Henry Fisher Raymond, DPH
Cui Yang (contact), PHD

Award e-mailed to: rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $739,827 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG089099. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$249,712
Fringe Benefits	$77,709
Personnel Costs (Subtotal)	$327,421
Consultant Services	$1,900
Materials & Supplies	$5,976
Travel	$3,800
Other	$10,925
Subawards/Consortium/Contractual Costs	$161,792
Federal Direct Costs	$511,814
Federal F&A Costs	$228,013
Approved Budget	$739,827
Total Amount of Federal Funds Authorized (Federal Share)	$739,827
TOTAL FEDERAL AWARD AMOUNT	$739,827
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$739,827

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$739,827	$739,827
2	$711,614	$711,614
3	$702,062	$702,062
4	$708,670	$708,670
5	$711,412	$711,412

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1226001086A1
Document Number:	RAG089099A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027	2028
AG	8470694	$739,827	$711,614	$702,062	$708,670	$711,412

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2BFAMGE / **OC**: 41021 / **Released**: 09/19/2024
Award Processed: 09/20/2024 12:16:23 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG089099-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG089099-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG089099. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-

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discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R01AG089099-01

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval.
No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.
******

This award includes funds awarded for consortium activity with **University of Pittsburgh** in the amount of $44,504 ($27,990 direct costs + $16,514 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15consortium_agreements.htm

This award includes funds awarded for consortium activity with **NJCRI** in the amount of $115,842 ($93,046 direct costs + $22,796 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:

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http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15consortium_agreements.htm
******

In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG089099-01

INSTITUTION: RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$249,712	$263,026	$259,606	$259,606	$249,711
Fringe Benefits	$77,709	$81,852	$80,788	$80,788	$77,709
Personnel Costs (Subtotal)	$327,421	$344,878	$340,394	$340,394	$327,420
Consultant Services	$1,900	$950	$950	$950	$2,850
Materials & Supplies	$5,976	$1,716			$977
Travel	$3,800	$25,793	$23,228	$27,287	$26,505
Other	$10,925	$4,275	$1,900	$4,275	$19,950
Subawards/Consortium/Contractual Costs	$161,792	$118,763	$126,701	$115,750	$110,962
Publication Costs				$4,750	$4,750
TOTAL FEDERAL DC	$511,814	$496,375	$493,173	$493,406	$493,414
TOTAL FEDERAL F&A	$228,013	$215,239	$208,889	$215,264	$217,998
TOTAL COST	$739,827	$711,614	$702,062	$708,670	$711,412

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	57%	57%	57%	57%	57%
F&A Cost Base 1	$400,022	$377,612	$366,472	$377,656	$382,452
F&A Costs 1	$228,013	$215,239	$208,889	$215,264	$217,998

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EXHIBIT C





03/20/2025

Gregory Werhner
RUTGERS BIOMEDICAL AND HEALTH SCIENCES
rsp-rbhs@research.rutgers.edu

Dear Gregory Werhner:

Effective with the date of this letter, funding for Project Number 5R01HL160326-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 09/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Anthony Agresti, Chief Grants Management Officer, National Heart, Lung, and Blood Institute
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT D

Department of Health and Human Services
National Institutes of Health
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Notice of Award
FAIN# R01HL160326
Federal Award Date
02/01/2023

Recipient Information

1. Recipient Name
RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST

NEWARK, 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

6. Recipient's Unique Entity Identifier
YVVTQD8CJC79

7. Project Director or Principal Investigator
Mackey R Friedman, PHD
Associate Professor
mf1061@rutgers.edu
973-972-1465

8. Authorized Official
Gregory Werhner

Federal Agency Information

9. Awarding Agency Contact Information
FATU Kamara
Grants Management Specialist
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
fatima.kamara@nih.gov
301-435-7916

10. Program Official Contact Information
Sean Coady
Program Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
coadys@mail.nih.gov
301-453-1289

Federal Award Information

11. Award Number
7R01HL160326-03

12. Unique Federal Award Identification Number (FAIN)
R01HL160326

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Stigma and the non-communicable disease syndemic in aging HIV positive and HIV negative MSM

15. Assistance Listing Number
93.837

16. Assistance Listing Program Title
Cardiovascular Diseases Research

17. Award Action Type
Change of Recipient Organization

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 02/01/2023 **– End Date** 08/31/2023	
20. Total Amount of Federal Funds Obligated by this Action	$716,170
20 a. Direct Cost Amount	$551,597
20 b. Indirect Cost Amount	$164,573
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$716,170
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$716,170
26. Project Period Start Date 02/01/2023 **– End Date** 08/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$716,170

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
John Diggs

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SECTION I – AWARD DATA – 7R01HL160326-03

Principal Investigator(s):
Mackey R Friedman, PHD

Award e-mailed to: rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $716,170 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number R01HL160326. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

John Diggs
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$9,715
Fringe Benefits	$5,998
Personnel Costs (Subtotal)	$15,713
Subawards/Consortium/Contractual Costs	$535,884
Federal Direct Costs	$551,597
Federal F&A Costs	$164,573
Approved Budget	$716,170
Total Amount of Federal Funds Authorized (Federal Share)	$716,170
TOTAL FEDERAL AWARD AMOUNT	$716,170
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$716,170

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$716,170	$716,170
4	$599,297	$599,297
5	$507,184	$507,184
6	$487,894	$487,894

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1226001086A1
Document Number:	RHL160326B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025
HL	8475158	$716,170	$599,297	$507,184	$487,894

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: HHEF A / **OC**: 41025 / **Released**: Diggs, John 01/27/2023
Award Processed: 02/01/2023 12:18:56 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 7R01HL160326-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 7R01HL160326-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.

b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HL160326. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HL SPECIFIC AWARD CONDITIONS – 7R01HL160326-03

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

CHANGE OF RECIPIENT INSTITUTION

This award reflects an approved change of recipient institution. The funds released by University of Pittsburgh are in accordance with the relinquishing statement dated December 1, 2022 and are an estimated balance. If the unobligated balance from University of Pittsburgh has been overestimated, it may be necessary to reduce the amount of this award.

NHLBI FUNDING GUIDELINES

This award is being issued in accordance with the NHLBI FY 2022 Operating Guidelines which can be found at: https://www.nhlbi.nih.gov/current-operating-guidelines

CONSORTIUM/CONTRACTUAL

This award includes funds awarded for consortium activity with the Georgetown University, Massachusetts General Hospital, Johns Hopkins University, University of Miami, Northwestern University, University of Alabama at Birmingham, The George Washington University, The Regents of the University of California, Los Angeles, University of Mississippi Medical Center, University of Pittsburgh, Hektoen Institute, and Whitman-Walker Institute, Inc.The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance

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project, the appropriate expenditures of grant funds by all parties, and all other obligations of the recipient, as specified in the NIH Grants Policy Statement. In general, the requirements that apply to the recipient, including the intellectual property requirements also apply to consortium participant(s).

MILESTONE ACCRUAL PLAN (MAP)
NHLBI support of this study is contingent upon adequate participant recruitment based on the recipient's Milestone Accrual Plan dated (9/8/21). The recipient is expected to demonstrate best effort compliance in accordance with the NHLBI Milestone Accrual Policy (https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/accrual-of-human-subjectsmilestones-policy.) Failure to achieve minimally acceptable milestone recruitment levels may result in the withholding of future support and/or negotiating an orderly close-out of this study.

FOREIGN COMPONENT
This award includes funding for the following foreign sites:

- Technische University Dresden (Dresden, Germany)

Any additions of foreign sites requires NIH prior approval.

FOREIGN TRAVEL
Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements.

PRIOR APPROVAL REQUEST
It is recommended that applicable prior approval requests be submitted via the eRA Commons Prior Approval Module (link: prior_approval (nih.gov)). Please refer to Part II Chapter 8 of the NIH Grants Policy Statement for the activities and/or expenditures that require NIH approval at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

NON-COMPETING RENEWAL (SNAP)
The NIH requires the use of the Research Performance Progress Report (RPPR) for all Type 5 progress reports. The RPPR and other documents applicable to this SNAP grant are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). Please see http://grants.nih.gov/grants/rppr/index.htm for additional information on the RPPR.

SPREADSHEET SUMMARY
AWARD NUMBER: 7R01HL160326-03

INSTITUTION: RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 3	Year 4	Year 5	Year 6
Salaries and Wages	$9,715	$1,889	$9,310	$4,183
Fringe Benefits	$5,998	$1,166	$5,748	$2,582
Personnel Costs (Subtotal)	$15,713	$3,055	$15,058	$6,765
Subawards/Consortium/Contractual Costs	$535,884	$579,117	$483,543	$477,273
TOTAL FEDERAL DC	$551,597	$582,172	$498,601	$484,038
TOTAL FEDERAL F&A	$164,573	$17,125	$8,583	$3,856
TOTAL COST	$716,170	$599,297	$507,184	$487,894

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Facilities and Administrative Costs	Year 3	Year 4	Year 5	Year 6
F&A Cost Rate 1	57%	57%	57%	57%
F&A Cost Base 1	$288,725	$30,043	$15,058	$6,765
F&A Costs 1	$164,573	$17,125	$8,583	$3,856

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EXHIBIT E





03/20/2025

Gregory Werhner
RUTGERS BIOMEDICAL AND HEALTH SCIENCES
rsp-rbhs@research.rutgers.edu

Dear Gregory Werhner:

Effective with the date of this letter, funding for Project Number 5R01HL160326-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 09/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Anthony Agresti, Chief Grants Management Officer, National Heart, Lung, and Blood Institute
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT F

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINOFIT# HEALTH ANR HEALTH RISPAFITIES

Notice of Award
8AINY F01MR01WJ69
Federal Award Date
05/16/2024

Recipient Information

1. Recipient Name
FUTGEFS THE STATE UNIVEFSIT# O8 NEB KEFSE#
J5 , EFGEN ST
STE 1
NEB AF73NK 06106

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
122J0010WJA1

4. Employer Identification Number (EIN)
22J0010WJ

5. Data Universal Numbering System (DUNS)
090299WQ0

’. Recipientǫs Uni7ue Entity Identifier
#VVTDRWCKC69

6. Project Director or Principal Investigator
Re(in English3PHR cConta) ty

de(in@nglish. rutgers@du
96Q-962-1655

8. Authorized Official
GregorwB erhner

Federal Agency Information

9. Awarding Agency Contact Information
SwSha) mleford

NATIONAL INSTITUTE ON MINOFIT# HEALTH ANR HEALTH RISPAFITIES
sha) mlefords. v ail@ih@o(
Q01-402-1QJJ

10. Program Official Contact Information
Crwstal , armsdale
Health S) ientist Adv inistrator/krograv Offi) ial
NATIONAL INSTITUTE ON MINOFIT# HEALTH ANR HEALTH RISPAFITIES
) rwstal@armsdale. nih@o(
Q01-402-1QJJ

Federal Award Information

11. Award Number
1F01MR01WJ69-01A1

12. Uni7ue Federal Award Identification Number (FAIN)
F01MR01WJ69

13. Statutory Authority
42 USC 241 42 C8F 52

14. Federal Award Project Title
Understanding the Fole of Stru) tural Okkression for Sui) ide Fismav ong , la) mSepual and Gender MinoritwAdoles) ents and #oung Adults

15. Assistance Listing Number
9Q@06

1’. Assistance Listing Program Title
MinoritwHealth and Health Riskarities Fesear) h

16. Award Action Type
Ne$ Cov keting

18. Is the Award R&D?
#es

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/16/2024 **– End Date** 12/Q1/2024	
20. Total Amount of Federal Funds Obligated by this Action	b6023145
20 a@Rire) t Cost Av ount	b5293 1W
20 x@Indire) t Cost Av ount	b16Q826
21. Authorized Carrwo(er	
22. Offset	
23. Total Av ount of 8ederal 8unds Oxligated this xudget keriod	b6023145
24. Total Approved Cost Sharing or Matching, where applicable	b0
25. Total Federal and Non-Federal Approved this Budget Period	b6023145
2’. Project Period Start Date 05/16/2024 **– End Date** 12/Q1/2026	
26. Total Av ount of the 8ederal A$ ard in) luding Akkro(ed Cost Sharing or Mat) hing this Proje) t Period	b6023145

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Pris) illa Grant

30. Remarks

A)) ektan) e of this a$ ard3in) luding the "Terv s and Conditions3 is a) mno$ ledged xwthe re) ikient $ hen funds are dra$ n do$ n or other$ ise requested frov the grant kawv ent swstev @

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Noti) e of A$ ard

RESEARCH
Rekartv ent of Health and Huv an Ser(i) es
National Institutes of Health

NATIONAL INSTITUTE ON MINOFIT# HEALTH ANR HEALTH RISPAFITIES

SECTION I – AWARD DATA – 1R01MD018’ 69-01A1

Principal Investigator(s):
Ranielle FeNaw, usxw8PHR
Re(in English c) onta) ty3PHR

Award e-mailed to: rsk-rxhs. resear) h@utgers@edu

Rear Authorized Offi) ial:

The National Institutes of Health herexwa$ ards a grant in the av ount of b6023145 csee “A$ ard Cal) ulation” in Se) tion I and “Terv s and Conditions” in Se) tion IIIy to FUTGEFS , IOMERICAL ANR HEALTH SCIENCES in sukkort of the axo(e referen) ed kroje) t@This a$ ard is kursuant to the authoritwof 42 USC 241 42 C8F 52 and is suxje) t to the requirev ents of this statute and regulation and of other referen) ed3in) orkorated or atta) hed terv s and) onditions@

A)) ektan) e of this a$ ard3in) luding the "Terv s and Conditions3 is a) nmo$ ledged xwthe re) ikient $ hen funds are dra$ n do$ n or other$ ise requested frov the grant kawv ent swstev @

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If wou ha(e anwquestions axout this a$ ard3klease dire) t questions to the 8ederal Agen) w) onta) ts@

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Pris) illa Grant
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NATIONAL INSTITUTE ON MINOFIT# HEALTH ANR HEALTH RISPAFITIES

Additional inforv ation follo$ s

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	bJW4JQ
Fringe Benefits	bQ23 09W
Personnel Costs (Subtotal)	b1003 5J1
Consultant Services	bQ43 000
Materials & Supplies	b93 55W
Travel	b13 594
Other	bJ63 JJ
Subawards/Consortium/Contractual Costs	bQ1J3 QQ9
Federal Direct Costs	b5293 11W
Federal F&A Costs	b16Q3 026
Approved Budget	b6023 145
Total Amount of Federal Funds Authorized (Federal Share)	b6023 145
TOTAL FEDERAL AWARD AMOUNT	b6023 145
AMOUNT OF THIS ACTION (FEDERAL SHARE)	b6023 145

SUMMARY TOTALS FOR ALL YEARS cfor this Ro) uv ent Nuv xery		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	b6023 145	b6023 145
2	bJ463 J0W	bJ463 J0W
Q	bJQQ3 460	bJQQ3 460
4	bJ253 604	bJ253 604

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Fiscal Information:

Payment System Identifier:	122J0010WJA1
Document Number:	FMR01WJ69A
PMS Account Type:	P cSuxa)) ounty
Fiscal Year:	2024

IC	CAN	2024	2025	202J	2026
MR	W462JW6	b6023 145	bJ463 J0W	bJQQ3 460	bJ253 604

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NIH Administrative Data:
PCC: CPS02 / **OC**: 41021 / **Released**: 05/10/2024
Award Processed: 05/16/2024 12:25:1J AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MD018’ 69-01A1

8or kaw ent and HHS Offi) e of Inske) tor General Hotline inforv ation3see the NIH Hov e Page at httk://grants@ih@o(/grants/koli) wa$ ard) onditions@tv

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MD018’ 69-01A1

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) @ 45 C8F Part 65@
d@ National Poli) wFequirev ents and all other requirev ents des) rixed in the NIH Grants Poli) w Statev ent3in) luding addenda in effe) t as of the xeginning date of the xudget keriod@
e@ 8ederal A$ ard Perforv an) e Goals: As required xwthe keriodi) rekort in the FPPF or in the final krogress rekort $ hen akkli) axle@
f@ This a$ ard noti) e3INCLURING THE TEFMS ANR CONRITIONS CITER , ELOB @

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Treatment of Program Income:

Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 1R01MD018' 69-01A1

Clini) al Trial Indi) ator: No

This a$ ard does not sukkort anwNIH-defined Clini) al Trials@See the NIH Grants Poli) wStatev ent Se) tion 1@2 for NIH definition of Clini) al Trial@

INFORMATION: In accordance with the National Institute on Minority Health and Health Disparities' (NIMHD's) Fiscal Year (FY) 2024 funding policies, this award has been issued at 85% of the adjusted requested level. Future year committed levels* have been adjusted accordingly.

*committed level: The level of support calculated by applying the NIMHD funding plan to the corrected recommended level for each budget category for all years of the project period.

REQUIREMENT: This award is subject to the conditions set forth in RFA-MH-22-140, Understanding Suicide Risk and Protective Factors among Black Youth (R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 03/22/2022, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-140.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: The awardee is required to follow the Data Management and Sharing Plan included in the 4/29/24 JIT and may not implement any changes in the plan without the written prior approval of the National Institute on Minority Health and Health Disparities.

INFORMATION: In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with a shortened budget period and with 12 months of support. Continuation awards will cycle each year on January 1st.

INFORMATION: Although the budget period start date for this award is May 17th, this award includes funds for 12 months of support. Future year budget periods will cycle on January 1st. Allowable pre-award costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, and with

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institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

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SPREADSHEET SUMMARY
AWARD NUMBER: 1F01MR01WJ69-01A1

INSTITUTION: FUTGEFS , IOMERICAL ANR HEALTH SCIENCES

, udget	#ear 1	#ear 2	#ear Q	#ear 4
Salaries and B ages	bJW84JQ	bJW84JQ	bJW84JQ	bJW84JQ
8ringe , enefits	bQ2309W	bQ2309W	bQ2309W	bQ2309W
Personnel Costs cSuxtotaly	b1003J1	b1003J1	b1003J1	b1003J1
Consultant Ser(i) es	bQ43000	b163000	b123650	b123650
Materials & Sukklies	b935W	b1Q3J6	bW860W	bW860W
Tra(el	b13594	b23Q96	b13199	b43652
Other	bJ63JJ	b653JJ	b693M J	b613Q1J
Suxa$ ards/Consortiuv /Co ntra) tual Costs	bQ1J3QQ9	bQ143606	bQ143606	bQ143606
TOTAL 8EREFAL RC	b52931W	b52Q3Q9W	b5163641	b5123694
TOTAL 8EREFAL 8&A	b16Q3026	b1243210	b1153629	b1123910
TOTAL COST	b6023145	bJ463J0W	bJQQ3460	bJ253604

8a) ilities and Adv inistrati(e Costs	#ear 1	#ear 2	#ear Q	#ear 4
8&A Cost Fate 1	56%	56%	56%	56%
8&A Cost , ase 1	bQ0Q3556	b2163910	b20Q3Q4	b19W8W6
8&A Costs 1	b16Q3026	b1243210	b1153629	b1123910

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EXHIBIT G

From: Bulls, Michelle G. (NIH/OD) [E]
To: Cathy Rivera
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:41 PM
Attachments: image002.png





3/24/2025

Cathy Rivera
Rutgers Biomedical And Health Sciences
carivera@ored.rutgers.edu

Dear Cathy Rivera:

Effective with the date of this letter, funding for Project Number 5R01AI158775-04 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 8/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations

imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT H

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI158775
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
RUTGERS THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST
STE 1
NEWARK, NJ 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

'. Recipient's Uni7ue Entity Identifier
YVVTQD8CJC79

6. Project Director or Principal Investigator
Jun Wang, PHD
Associate Professor
junwang@pharmacy.rutgers.edu
848-445-6493

8. Authorized Official
Cathy Rivera
carivera@ored.rutgers.edu
848-932-1080

Federal Agency Information

9. Awarding Agency Contact Information
FABIOLA Chacon
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
fabiola.chacon@nih.gov
301-761-7938

10. Program Official Contact Information
Mary Katherine Bradford Plimack

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
kate.plimack@nih.gov
(240) 447-9748

Federal Award Information

11. Award Number
5R01AI158775-04

12. Uni7ue Federal Award Identification Number (FAIN)
R01AI158775

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Development of dual inhibitors targeting the viral main protease and the host cathepsin L as SARS-CoV-2 antivirals

15. Assistance Listing Number
93.855

1'. Assistance Listing Program Title
Allergy and Infectious Diseases Research

16. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2023 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$730,106
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$730,106
2'. Project Period Start Date 01/04/2022 **– End Date** 03/24/2025	
26. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,864,117

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI158665-04 RE: ISED

Principal Investigator(s)/
Jun Wang, PHD

Award e-mailed to/ rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI158775. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$107,786
Fringe Benefits	$50,310
Personnel Costs (Subtotal)	$158,096
Materials & Supplies	$92,661
Travel	$2,000
Other	$6,414
Subawards\Consortium\Contractual Costs	$294,716
Tuition Remission	$14,242
Federal Direct Costs	$568,129
Federal F&A Costs	$161,977
Approved Budget	$730,106
Total Amount of Federal Funds Authorized (Federal Share)	$730,106
TOTAL FEDERAL AWARD AMOUNT	$730,106
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARV TOTALS FOR ALL VEARS (for this Document Number)		
VR	**THIS AWARD**	**CUMULATI: E TOTALS**
4	$730,106	$730,106

Fiscal Information/

Payment System Identifier/	1226001086A1
Document Number/	RAI158775BC6
PMS Account Type/	P (Subaccount)
Fiscal Vear/	2023

IC	CAN	2023
AI	8055771	$730,106

NIH Administrative Data/
PCC: M51C SR / **OC**: 41025 / **Released**: 03/25/2025
Award Processed/ 03/26/2025 12:03:39 AM

SECTION II – PAVMENTYHOTLINE INFORMATION – 5R01AI158665-04 RE: ISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI158665-04 RE: ISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D)/ All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI158775. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted

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electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income/
Additional Costs

SECTION I: – AI SPECIFIC AWARD CONDITIONS – 5R01AI158665-04 RE: ISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

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NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes previous Notice of Award dated **07/02/2024**. All other terms and conditions still apply to this award.

****
REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the -14 year as agreed to in the correspondence dated **6/10/2024**. This is the only mid-project extension that will be allowed for the remainder of the project period.

This award also removes the no-cost extension authority of the NIH Standard Terms and Conditions of Award. NIAID prior approval is required to extend the project period end date for this award.

Supersedes previous Notice of Award dated **5/26/2023**. All other terms and conditions still apply to this award.

****
This award provides funds of **$730,106** Total Costs (**$568,129** Direct Costs and **$161,977** F&A Costs) to prevent, prepare for, and respond to viral variant or disease with potential for creating a pandemic, domestically or internationally. These funds provide support for the period **08Y01Y2023-06Y31Y2024.** These funds are restricted to prevent, prepare for, and respond to coronavirus domestically or internationally only as described in the application submitted **on 06/12/2020** and subsequent documentation submitted **05/12/2023**, and may not be rebudgeted or used for any other purpose without NIAID prior approval.

****
This Notice of Award (NoA) includes funds for **Oklahoma State University.**
This Notice of Award (NoA) includes funds for **University of Arizona.**
This Notice of Award (NoA) includes funds for **University of South Florida.**

****

Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

> If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

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If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.

If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

SPREADSHEET SUMMARV
AWARD NUMBER/ 5R01AI158775-04 REVISED

INSTITUTION/ RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 4
Salaries and Wages	$107,786
Fringe Benefits	$50,310
Personnel Costs (Subtotal)	$158,096
Materials & Supplies	$92,661
Travel	$2,000
Other	$6,414
Subawards/Consortium/Contractual Costs	$294,716
Tuition Remission	$14,242
TOTAL FEDERAL DC	$568,129
TOTAL FEDERAL F&A	$161,977
TOTAL COST	$730,106

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	57%
F&A Cost Base 1	$284,171
F&A Costs 1	$161,977

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EXHIBIT 21

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF KATIE TRACY

I, KATIE TRACY, declare under the penalty of perjury, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct to the best of my knowledge:

1. I am the EXECUTIVE DIRECTOR OF SPONSORED PROJECTS for the UNIVERSITY OF NEVADA, RENO (the "UNIVERSITY"). I am familiar with the information in the statements set forth below, either through personal knowledge, in consultation with UNIVERSITY staff, or from documents that have been provided to and/or reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the EXECUTIVE DIRECTOR OF SPONSORED PROJECTS at the UNIVERSITY and have been in my role for approximately eighteen (18) months. I have worked in the sponsored projects field for approximately five (5) years.

4. The UNIVERSITY's statutory mission is to provide outstanding learning, discovery, and engagement programs that serve the economic, social, environmental and cultural

needs of the citizens of Nevada, the nation, and the world. The University recognizes and embraces the critical importance of diversity in preparing students for global citizenship and is committed to a culture of excellence, inclusion, and accessibility.

5. The UNIVERSITY has one campus, 23,029 students (as of Fall 2024), 868 researchers and 2,320 research support staff and technicians.

6. I am providing this declaration to explain the impacts of National Institutes of Health ("NIH") delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts the UNIVERSITY, delaying over $177 million in pending and competitively scored grant proposals. These delays have paused faculty hiring, reduced graduate admissions, disrupted research timelines, and created significant budget uncertainty, with potential losses ranging from $9.5 to $30 million. The breakdown in NIH's review and award process is undermining the UNIVERSITY's ability to sustain biomedical research, train the future STEM workforce, and support public health initiatives across Nevada.

Reliance on NIH Funding

8. In fiscal year 2024, the UNIVERSITY received funding through the NIH to support 27 projects, totaling $9,584,629.

9. The UNIVERSITY receives NIH grants across a variety of institutes encompassed within the NIH, including: National Cancer Institute; National Eye Institute; National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis, Musculoskeletal and Skin Diseases; National Institute of Child Health and Human Development; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute of Drug Abuse; National Institute of Environmental Health Sciences; National Institute of General Medical Sciences; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; National Institute on Aging; National Institute on Deafness and Other Communication Disorders; National Institute on Minority Health and Health Disparities; and National Institutes of Health.

10. Through those NIH grants, the UNIVERSITY funds 87 researchers.

11. The work done by the UNIVERSITY on NIH-funded projects provides education and training in Bioengineering and Biomedical Engineering, Chemical Engineering, Mechanical Engineering, Metallurgical and Materials Engineering, Agricultural Sciences, Biological and Biomedical Sciences, Health Sciences, Chemistry, Physics, and Psychology.

12. The UNIVERSITY provides considerable employment benefits to the Science, Technology, Engineering and Mathematics ("STEM") workforce and to Nevada's economy.

Typical Timeline and Processes for NIH Grant Awards

13. The Division of Research and Innovation at the UNIVERSITY works with researchers to submit grant applications and tracks grant applications and awards.

14. Based on my work as EXECUTIVE DIRECTOR OF SPONSORED PROJECTS and in other roles over the last five (5) years, I have an understanding of the NIH grant process.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at the UNIVERSITY relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 6 months of submission.

20. Once a grant receives a score, the UNIVERSITY is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

21. Since late January 2025, the UNIVERSITY has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils cancelled or not scheduled, and grant application scoring has been significantly delayed.

22. The UNIVERSITY has not received formal notice of changes for many of these grants. For others, the UNIVERSITY has gotten only a notification that proposals are "paused" or "under review."

23. As of March 31, 2025, the UNIVERSITY has approximately 41 proposals totaling $87.8M awaiting NIH study section review.

24. As of March 31, 2025, the UNIVERSITY has 36 proposals totaling $90.0M that received fundable scores awaiting NIH advisory council and Notice of Award.

25. As of March 31, 2025, the UNIVERSITY has 8 proposals totaling $6.8M that received possibly fundable scores awaiting NIH advisory council and Notice of Award.

Comparisons Across Administrations

26. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or breakdowns.

27. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

28. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

29. Delays by NIH through failure to publish have impacted budget cycles and the ability to financially forecast. Based on FY2024 new awards, we estimate that no Notices of Award will result in an impact of at least $9.5 million. The higher-end estimate of the potential impact is approximately $30 million, representing about 12% of currently pending proposals.

30. We have paused start-up funding for new hires whose research programs depend on timely NIH awards. This includes several new hires we had provided offer letters to and for whose arrival the UNIVERSITY had taken steps to prepare.

31. Several shared research cores have seen decreased usage due to grant uncertainty, and one facility temporarily reduced staff hours due to budget delays.

Effects on Admissions, Training and Workforce Disruptions

32. The UNIVERSITY uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

33. The UNIVERSITY has had to reduce its incoming class of graduate students by approximately 5-10% due to uncertainty over incoming grant funding because of the delays in reviewing and awarding grants by NIH.

34. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

35. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the

research capabilities of the UNIVERSITY, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

36. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

37. Several major proposals from our institution remain stuck at the preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

38. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

39. The delays have disrupted ongoing research and are setting back the UNIVERSITY for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

40. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding.

41. Delays have also disrupted community services, student opportunities, and public programs.

42. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

43. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are

undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



KATIE TRACY

Date: 4/2/2025

EXHIBIT 22

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF DAVID W. HATCHETT

I, David W. Hatchett, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Institutional Officer and Vice President for Research of the University of Nevada, Las Vegas. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the University of Nevada, Las Vegas staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration supporting the States' Motion for Temporary Restraining Order.

Professional Background

3. I am David W. Hatchett, and I currently serve as the Institutional Officer and Vice President for Research at the University of Nevada, Las Vegas. I am also a veteran researcher with over 25 years of experience and hold a PhD in Physical/Analytical Chemistry.

4. The University of Nevada, Las Vegas's statutory mission is to improve the lives of diverse students, transform communities through education and engagement, provide access to

world-class educational experiences, engage in groundbreaking research, and offer high-value, cutting-edge interdisciplinary physical and mental health care.

5. The University of Nevada, Las Vegas Main and Health campuses have a total of 29,899 students enrolled with 745 tenure track faculty performing research, a number of grant funded graduate students and postdocs.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts the University of Nevada, Las Vegas, by influencing the submission of grant applications, evaluation of grant applications, and current research under consideration.

Reliance on NIH Funding

8. In the fiscal year 2024, the University of Nevada, Las Vegas received funding through the National Institutes of Health ("NIH") to support twenty-nine projects, totaling $11,964,257.

9. The University of Nevada, Las Vegas, receives NIH grants across various institutes within the NIH, including the Institute on Aging, General Medical Sciences, Environmental Health Sciences, Drug Abuse, Allergy, and Infectious Diseases.

10. Through those NIH grants, the University of Nevada, Las Vegas funds twenty-one researchers.

11. The work done by the University of Nevada, Las Vegas, on NIH-funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs.

12. The University of Nevada, Las Vegas, provides considerable employment benefits to the state's economy in the Science, Technology, Engineering, and Mathematics ("STEM") workforce.

Typical Timeline and Processes for NIH Grant Awards

13. The Office of Sponsored Programs at the University of Nevada, Las Vegas, works with researchers to submit and track grant applications and awards.

14. Based on my work as the Vice President for Research and consultation with the Executive Director of the Officer of Sponsored Programs, I understand the NIH grant process based on my 10 years of experience in the Division of Research.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the

standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at the University of Nevada, Las Vegas, relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within six months of submission.

20. Once a grant receives a score, University of Nevada, Las Vegas is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

21. Since late January 2025, the University of Nevada, Las Vegas, has seen unusual delays in processing NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or not scheduled, and grant application scoring has been significantly delayed.

22. The University of Nevada, Las Vegas, has not received formal notice of changes for many of these grants. For others, it has received only a notification that proposals are "paused" or "under review."

23. As of March 28, 2025, the University of Nevada, Las Vegas, has approximately forty-two proposals totaling $65.68 million awaiting NIH study section review.

24. As of March 28, 2025 the University of Nevada, Las Vegas, has not received any information regarding fundable scores and is awaiting NIH advisory council Notice of Awards.

Terminations of NIH Grants

25. Since March 1, 2025, three NIH grants have been terminated at the University of Nevada, Las Vegas.

26. The terminations were received as of March 28, 2025.

27. These terminations will result in the loss of $2.40 million in research money to the University of Nevada, Las Vegas.

28. The termination notices for these grants have provided very little explanation, instead noting that the research no longer "effectuates agency priorities." While at the University of Nevada, Las Vegas, I have not previously seen this language used to cancel grants. Similarly, the language has not been observed in the termination of grants by the Executive Director of the Office of Sponsored Programs in 8 years in grant administration.

29. The termination notices have also stated that no corrective action can be taken to ensure the grant aligns with agency priorities. However, prior to the receipt of the termination, the University of Nevada, Las Vegas, had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was the University of Nevada, Las Vegas, provided with any updated "agency priorities" with which its research must align.

30. All of these projects were focused on Alzheimer's Disease and advancing research in this critical health need. High-level description of the terminated grants, including their

research aims, any research breakthroughs achieved, benchmarks achieved/reported through RPPRs.

Comparisons Across Administrations

31. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

32. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

33. Terminations were exceedingly rare and followed due process. In our experience, the current approach is without precedent.

Impact on Institutional Operations

34. Grant terminations, lack of determination on grant applications, and uncertainty in funding priorities significantly impact our ability to forecast the budget cycle based on unreasonable delays by NIH and through failure to publish.

35. These delays have not forced us to implement bridge funding as of March 31, 2025. However, bridge funding for student graduate assistants has been allocated by the University of Nevada, Las Vegas to ensure their continued support.

Effect on Public-Facing or State-Supported Programs

36. The grant terminations by NIH have reduced individuals' access to Alzheimer's research and findings.

Admissions, Training and Workforce Disruptions

37. The University of Nevada, Las Vegas, uses that information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

Concerns About FY25 Funds Being Obligated

38. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

39. Several major proposals from our institution remain stuck at preliminary review stages, and there is no indication that the required advisory reviews or notices of award will occur in time.

40. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns." However, we do not have an accurate understanding of what programs have been delisted and will not continue.

Irreparable Harm

41. The delays have disrupted ongoing research and are a setback for the University of Nevada, Las Vegas for research going forward. The lack of clarity has made researchers abandon studies, miss deadlines, and lose key personnel as funding supports these endeavors. The delays and lack of clarity regarding NIH funding diminish the long-term planning and priorities of research established by colleges at the University of Nevada, Las Vegas.

42. Some studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding.

43. Delays have disrupted community services, student opportunities, and public programs.

44. Once disrupted, in many cases, lost time, research continuity, or training value cannot be recovered.

Conclusion

45. The breakdown in NIH processes affects institutional operations, planning, and public health partnerships. Terminations and delays without explanation or remedy undermine confidence in the system. These harms are ongoing and, in many instances, irreparable.

David W. Hatchett

David W. Hatchett
Date: 03/31/2025

EXHIBIT 23

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF TIMOTHY F. MURPHY

I, Timothy F. Murphy, MD, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the University at Buffalo staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am a senior associate dean for clinical and translational research, responsible for overseeing strategies that aim to transform the University at Buffalo's research programs into new or improved treatments for patients and for assisting faculty and trainees at all levels in their research activities. I also direct the University's Clinical and Translational Science Institute, a facility that includes a nine-bed Clinical Research Center with support services for clinical

research. A wide variety of clinical and translational research training programs are conducted and coordinated at the facility.

An internationally recognized expert in respiratory tract bacterial infections, I am a SUNY Distinguished Professor of medicine and microbiology and immunology. I specialize in research on pathogens responsible for ear infections (primarily in children) and on lower respiratory tract infections in adults with chronic obstructive pulmonary disease (COPD).

I hold more than a dozen patents related to vaccine development and conducted the longest-standing study of COPD at the Buffalo Veterans Affairs Medical Center from 1994 to 2014. My laboratory is based at the University's Clinical and Translational Science Institute, and my work has long been funded in part by grants from the National Institutes of Health.

A graduate of New York University, I received my medical degree from Tufts University School of Medicine, completed an internship and residency in internal medicine at the New York Hospital Cornell Medical Center, and completed a fellowship in infectious diseases at Tufts before coming to the University at Buffalo in 1981. I have published 230 articles in peer-reviewed journals and serve as a reviewer for 20 medical journals, including the New England Journal of Medicine.

4. The University at Buffalo is a scholarly community dedicated to bringing the benefits of our research, scholarship, creative activities and educational excellence to local and global communities in ways that impact and positively change the world.

The University views the three traditional pillars of the public higher education mission—research, education and service—as interdependent endeavors that continually enrich and inform each other. Groundbreaking research, transformative educational experiences and

deeply engaged service to our communities define the University at Buffalo's mission as a premier, research-intensive public university.

5. University at Buffalo has three campuses, over 32,000 students, almost 12,000 employees, and performs over $544,000,000.00 in vital research annually.

Reliance on NIH Funding

6. In fiscal year 2024, University at Buffalo received funding through the National Institutes of Health ("NIH") to support 224 projects, totaling $60,654,347.

7. University at Buffalo receives NIH grants across a variety of institutes encompassed within the NIH, including the National Institute on Minority Health and Health Disparities, the National Institute of Mental Health, and the National Institute for Alcohol Abuse & Alcoholism.

8. Through those NIH grants, University at Buffalo funds 1003 researchers.

9. The work done by University at Buffalo on NIH funded projects provides education and training in Biomedical Engineering, Biochemistry, Chemistry, Dentistry, Family Medicine; Internal Medicine; Microbiology and Immunology, Neurology, Nursing, Ophthalmology, Pathology, Pediatrics, Pharmacology, Psychology, Public Health and Health Professions, Radiology, and other programs.

10. University at Buffalo provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New York State economy.

Terminations of NIH Grants

11. Since March 12, 2025 University at Buffalo has had three NIH grants terminated, not including terminated grants for which the University was a sub-awardee.

12. The terminations received as of March 28, 2025 are attached hereto as Exhibits A–C.

13. These terminations will result in the loss of at least $4,481,711 in research money to University at Buffalo.

14. The termination notices for these grants have provided very little to explain the termination, instead noting that the research is no longer consistent with newly conceived agency priorities. Specifically, the termination notices state that: "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."

15. In my 44 years working at University at Buffalo, my research has been continuously funded by the NIH for 42 of those years. I have never had a grant canceled by the NIH and have never seen this language to cancel grants.

16. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, University at Buffalo had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was University at Buffalo provided with any updated "agency priorities" with which its research must align.

17. The NIH grant, "Center of Excellence in Investigator Development and Community Engagement" (grant number 1P50MD019473-01) to the University at Buffalo that was canceled March 13, 2025 has research aims that align directly with the publicly stated NIH mission, which is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

18. One aim of the Center of Excellence grant is to train and mentor a new generation of scientists from a broad range of disciplines to perform innovative research to improve public health with an emphasis in our region, more specifically in Erie County, located in Western New York. To accomplish this aim, the grant provides pilot study funds to early-stage investigators (using the NIH definition of early-stage investigators) to perform innovative research designed to improve health in our region in ways that are sustainable. The grant also includes effort for training experiences and mentoring tailored to the early-stage investigators to advance their careers. This aim directly addresses one of the publicly stated goals of the NIH: "to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease" by expanding the nation's health research workforce and improving health through training the next generation of research leaders in public health.

19. The grant has met and exceeded all milestones in the first seven months of funding with outstanding progress. To attract the most accomplished early-state investigators to apply for pilot studies, a Request for Applications was circulated to faculty in all 12 UB schools in an effort to engage researchers in many disciplines. The rationale is that improving public health will require expertise in both health-related and nonhealthy related disciplines, including for example urban planning (built environment and neighborhoods), education (improving health

literacy, which is directly related to health), economics (addressing poverty), and more. We received 18 Letters of Intent (LOIs) from early-stage investigators across seven UB schools, including the Jacobs School of Medicine and Biomedical Sciences, School of Public Health and Health Professions, School of Nursing, School of Management, School of Engineering and Applied Sciences, and College of Arts Sciences, and Graduate School of Education. This was an excellent outcome in that we reached a substantial number of early career researchers with interest in health-related research. Importantly, these applicants were from a broad range of disciplines, which was one our goals.

20. Based on review by the pilot studies review committee, 11 applicants were invited to submit full proposals. Using a rigorous review process that involved a study section-like review and discussion of each proposal, pilot study grants were awarded to four early-stage faculty. Briefly, the four projects address public health issues that are especially important in our region:

a. Promoting health in elementary schools in Buffalo Public Schools by researchers from the UB School of Public Health and Health Professions and the Graduate School of Education.

b. Development of cell phone app to increase health literacy and improve access to healthcare for obstetric patients to improve maternal and neonatal outcomes from an expert in human-computer interaction from the School of Engineering and Applied Sciences.

c. Placing community health workers in pediatric practices to increase access to healthcare for families and children from a pediatrician in the Jacobs School of Medicine and Biomedical Sciences.

d. Promoting and teaching bystander cardiopulmonary resuscitation in schools and communities by a team from the Jacobs School of Medicine and Biomedical Sciences.

21. All four of these projects support a publicly stated goal of the NIH: "to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health."

22. Of the 62 counties in New York State, Erie County (population 950,683) is ranked 47th based on data from the New York State Department of Health and county health departments. The long-term goal of this grant is to support innovative research that will improve health outcomes in Erie County while training the generation of the nation's public health research leaders. The pilot studies supported by the Center of Excellence grant and larger projects that will result from the pilot studies will improve health in our region.

23. Leadership of the Investigator Development Core of the Center of Excellence grant met with each pilot study awardee and their departmental research administrator in a training session to review requirements, conditions of funding and to address any questions. The Core is assisting pilot study awardees to ensure compliance with federal policies, rules, and guidelines for research involving human subjects.

Comparisons Across Administrations

24. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

25. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

26. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

27. The termination of the Center of Excellence grant at this time is particularly devastating for early-stage faculty whose research is supported by the grant. The highest risk period in the career of a health sciences and public health researcher is the transition from training to their first faculty position. This time period is frequently the turning point in one's career, determining whether they will become a successful, established researcher with their own independent federal funding or not. The early-stage faculty funded by this grant were all in the initial phase of initiating their study, including receiving Institutional Review Board (IRB) approval for human studies, hiring personnel and graduate students to work on their projects, training the new personnel and establishing protocols and partnerships. All of this successful activity has been stopped abruptly by termination of the Center of Excellence Grant (1P50MD019473-01) putting their research and their careers in jeopardy.

28. We have paused seed funding for early career faculty related to this award as their projects depend on timely NIH awards. This funding was considered in the hire of new faculty related to the award intent and whom we had provided offer letters to and for whom the University at Buffalo had taken steps to prepare for their arrival. Termination of this award has a compounding affect on not only the faculty, but a strategic growth investment for the university.

29. Several shared research cores have seen decreased usage due to grant uncertainty, and one facility temporarily reduced staff hours due to budget delays.

Admissions, Training and Workforce Disruptions

30. University at Buffalo uses that information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

31. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

32. Physician scientists are an especially critical part of the health sciences workforce supported by NIH training grants. There is an alarming national decline in physician-scientists in the last three decades. Physician-scientists are a vital component of the biomedical research workforce. Combining both clinical and research expertise, physician-scientists play an irreplaceable role in biomedical discovery by bringing unique perspectives through caring for patients. Physician-scientists have been awarded 41% of basic and 65% of clinical Lasker Awards; 37% of all Nobel Prizes in Physiology or Medicine have gone to physician-scientists. Physician-scientists are also important leaders in scientific organizations, representing ~70% of NIH Directors and~ 70% of scientific officers in the largest pharmaceutical companies. Taken together, physician-scientists are a critical asset in the US and the world.

33. In the 1980s, physicians engaged in research reached a peak of 4.7% of the physician workforce. Today, only 1.5% of physicians in the US report research as their major professional activity. The number of physician scientists receiving postdoctoral research training and career development awards is at an all-time low. Early career physicians currently make up a smaller share of funded investigators than ever, and the training pipeline for future physician scientists is shrinking. The report by the NIH Physician Scientist Working Group made a series

of recommendations aimed toward increasing the number of physician scientists in the biomedical research workforce, emphasizing the national priority placed on training more physician scientists. The report concludes that in order to maintain a steady state, 1,000 physician scientists per year will need to enter the workforce.

34. Four physician scientists are principal investigators or co-investigators on the pilot studies awarded as part of the Center of Excellence grant. The abrupt termination of this grant will clearly adversely impact career development for these faculty at the most vulnerable time in their scientific careers.

Irreparable Harm

35. The terminations have disrupted ongoing research, as well as setting back the University at Buffalo for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the interim funding measures being taken by University at Buffalo to keep certain research going. University at Buffalo has had to make decisions about which of these valuable programs to continue with these limited funds.

36. Delays have also disrupted community services, student opportunities, and public programs.

37. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

38. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are

undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

39. The termination of the NIH P50 grant has caused significant disruptions to research, faculty development, and institutional operations at the University at Buffalo. Early-stage faculty, who were relying on this funding to establish their independent research careers, now face major setbacks, including stalled projects, lost personnel, and diminished prospects for securing future funding. Several pilot studies aimed at improving public health in Western New York have also been halted, delaying critical advancements in community health initiatives. The sudden loss of funding has forced the University to reallocate limited discretionary resources for emergency bridge funding, diverting support from other research priorities and planned institutional improvements.

40. Beyond the immediate research impact, these terminations have destabilized faculty recruitment, reduced access to shared research facilities, and weakened the training pipeline for future scientists, including physician-scientists. The unpredictability of NIH funding has created institutional uncertainty, delaying new faculty start-ups and diminishing confidence in the reliability of federal research support. With loss of key personnel related to the efforts, substantial previous investments made both by the U.S. Department of Health and Human Services and the University will be a complete loss as disruption of an established team does not permit others to step in and complete the work proposed. Many of these harms—particularly lost time, disrupted research continuity, and career setbacks—are irreparable..



Timothy F. Murphy MD

Date: 4-1-25

EXHIBIT A



March 12, 2025

Amy Lagowski
Research Foundation for the State University of New York
Amy.Lagowski@buffalo.edu

Dear Amy Lagowski:

Funding for Project Number 1P50MD019473-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 19, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 22:17:03 -04'00'

Michelle G. Bulls, on behalf Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT B

Wshen7@buffalo.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:31 PM
To: Wei Shen <wshen7@buffalo.edu>
Subject: Grant Termination Notification



3/21/2025

Wei Shen
State University Of New York At Buffalo
wshen7@buffalo.edu

Dear Wei Shen:

Effective with the date of this letter, funding for Project Number 5K01MH130270-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents [12]

supporting your claim.

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT C



3/21/2025

Mical, Alison
State University Of New York At Buffalo
alodojew@buffalo.edu

Dear Mical, Alison:

Effective with the date of this letter, funding for Project Number 5R01AA028810-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 24

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF SCOTT E. SHURTLEFF

I, Scott E. Shurtleff, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Sponsored Programs and Regulatory Affairs of The Research Foundation for The State University of New York (RF). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the RF and State University of New York staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am Vice President for Sponsored Programs and Regulatory Affairs for The Research Foundation for The State University of New York (RF), a role I have held since June 2020, before which I was the Associate Director for Grants, Contracts and Pre-Award since October 2017. Prior, I was Senior Associate Counsel in the RF Office of General Counsel starting in May 2013. Before coming to the RF, I had 20 years of sponsored research program

experience: I was Co-Director of sponsored programs at the State University of New York, University at Buffalo, a Research Center Manager at the London School of Economics, Manager of the Research Grants Office at University of York, and worked for Massachusetts Institute of Technology (MIT) for eight years in three roles including as Assistant Director for Finance and Administration for the Cambridge-MIT Institute, Manager for Finance and Administration for the Industrial Performance Center and as an administrator with the MIT-China program. I also worked in private law practice for six years. I earned my bachelor's degree from the Syracuse University School of Management and my law degree from Boston University.

4. RF is the largest comprehensive university-connected research foundation in the country. It provides essential administrative services that enable SUNY faculty to devote themselves to SUNY's core mission of educating students and conducting life-changing research. RF was chartered in 1951 by the New York State Board of Regents as a non-profit education corporation. RF writes and submits grant proposals to agencies, foundations, and companies; establishes contracts and manages funding awarded to run campus-based research projects; protects and commercializes intellectual property created within those projects; and establishes enduring partnerships to advance research and research commercialization

5. The SUNY System is comprised of 64 colleges and universities, 29 of which are directly operated by the State of New York. Of those, four SUNY campuses are designated R1 research institutions: Binghamton University; Stony Brook University; University at Albany; and University at Buffalo.

6. I am providing this declaration to explain the impacts of NIH's abrupt and summary termination of issued grants, delays and/or cancellation of study sections and advisory council meetings.

Reliance on NIH Funding

7. In fiscal year 2024, the Research Foundation for SUNY received funding through the National Institutes of Health ("NIH") to support 894 projects, totaling $237.5 million.

8. The Research Foundation for SUNY receives NIH grants across a variety of institutes encompassed within the NIH, including 24 NIH Institutes.

9. Through those NIH grants, the Research Foundation for SUNY funds 859 Researchers, including both principal investigators (PIs) and co-principal investigators (co-PIs).

10. The work done by SUNY research faculty on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs of benefit to the American public.

11. SUNY and The Research Foundation for SUNY provide considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New York economy.

Typical Timeline and Processes for NIH Grant Awards

12. The Research Foundation works with SUNY researchers to submit grant applications and receives awards on behalf of SUNY institutions.

13. Based on my eight years of experience as Vice President for Sponsored Programs and Regulatory Affairs and as Associate Director for Grants, Contracts and Pre-Award, I have an understanding of the NIH grant process. NIH grant applications are typically submitted via NIH's online portal, usually in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the

grant will be funded.

14. What constitutes a fundable score is dependent on several factors as every institute is different. Most of the standing study sections result in an impact score and percentile for each proposal, but many others will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives.

15. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

16. The process for competitive renewals is very similar.

17. The budget process at SUNY campuses relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 9-12 months of submission.

18. Once a grant receives a score, a SUNY campus is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

19. Since late January 2025, SUNY has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

20. SUNY faculty have not received formal notice of changes for many of these grants. For most, SUNY faculty have gotten only a notification that proposals are "under review."

Terminations of NIH Grants

21. Since March 12, 2025, SUNY has received notices of termination of at several NIH grants.

22. The termination of these grants in mid-term will result in the loss of over $4.5 million which is the total funding still available on the terminated awards as of the date of termination. NIH Award Number 1P50MD019473-01, *"Igniting Hope in Buffalo New York Communities, Training the Next Generation of Health Equity Researchers"* ("UB Project") was issued to the Research Foundation on behalf of the University of Buffalo (UB) on July 19, 2024. The Notice of Award is attached hereto as Exhibit A. The term of the award was five years (ending on June 30, 2029) with total funding of $3,596,263 over the term. Of the first-year funding of $724,502, $128,305 has been spent to date. UB Distinguished Professor of Medicine. Timothy F. Murphy, MD of the Jacobs School of the Jacobs School of Medicine and Biomedical Sciences is the principal investigator (PI) on the award.

23. Dr. Murphy submitted a proposal in response to a Notice of Funding Opportunity (RFA-MD-23-11) (NOFO) issued by the National Institute on Minority Health and Health Disparities (NIMHD) on May 24, 2023. NOFO RFA-MD-23-11 is attached hereto as Exhibit B.

24. The mission of NIMHD as described in the NOFO is: "[t]o conduct and support research, training, health information dissemination, and other programs with respect to minority health and health disparities. This funding opportunity seeks to facilitate the education of participants from diverse backgrounds, including those underrepresented in biomedical research to pursue clinical research, translational and/or patient-oriented research, particularly on diseases that disproportionately impact populations that experience health disparities https://www.nimhd.nih.gov/about/overview/".

25. The website referenced in paragraph 33 remains live and further provides that "[m]any populations in America, whether defined by race, ethnicity, immigrant status, disability, sex, or geography, experience higher rates of certain diseases and more deaths and suffering from them compared with the general population. While the diversity of the American population is one of the nation's greatest assets, one of its greatest challenges is reducing the profound disparity in health status of its racial and ethnic minority, rural, low-income, and other underserved populations Through NIMHD's leadership, health disparities have become a recognized scientific field of study, which has evolved from documenting and investigating differences in health status and risk factors among affected populations, to addressing health disparities using traditional and non-traditional research approaches." https://www.nimhd.nih.gov/about/overview/ (last visited March 29, 2025).

26. UB's successful proposal, entitled *Igniting Hope in Buffalo New York Communities, Training the Next Generation of Health Equity Researchers,* attached hereto as Exhibit C is a 273-page document proposing to establish the University at Buffalo Center of Excellence in Investigator Development and Community Engagement with a goal "to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community." Exhibit C at 66. The Center of Excellence would have supported "a transdisciplinary framework that cuts across scientific and organizational silos to integrate disciplines to address the full range of social determinants of health and to mentor early-career investigators in research in health disparities."

27. NIH Award Number 5K01MH130270-03, *Intersectional minority stress, mental health, and HIV treatment and care among MSM living with HIV in Ghana,* was issued to the Research Foundation on behalf of the University of Buffalo on August 1, 2022, for a five-year duration ending on July 31, 2027. The total funding for the award is $863,125. The PI on the

award is Dr. Akua Gyamerah, Assistant Professor of Community Health and Health Behavior in the UB School of Public Health and Health Professions.

28. As defined in the Notice of Funding Opportunity PA-20-190 issued by the National Institute for Mental Health, "the purpose of the NIH Mentored Research Scientist Development Award (K01) is to provide support and protected time (three to five years) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence." NOFO PA-20-190 is attached as Exhibit D.

29. As noted in the Project Abstract Summary, the project is focused on health disparities. It states "[i]n Ghana, MSM bear a high HIV burden, yet less than 4% of HIV-positive MSM are on antiretroviral therapy—a disparity found throughout Africa. Social stressors, such as sexuality- and gender-based stigma, criminalization, and violence, have been linked to both poor mental health and HIV outcomes and may be barriers to optimal HIV service engagement among African MSM."

30. NIH Award number R01AA028810-01A1, "*Peer Victimization and Risky Alcohol Use among Sexual Minority Youth: Understanding Mechanisms and Contexts*" was issued to the Research Foundation on behalf of the University of Buffalo on November 3, 2020. Dr. Amy Hequembourg, associate professor at the State University of New York University at Buffalo in the School of Nursing, is the PI on the award. To date $1,924,939 of $2,351,707 in total award funding has been expended, leaving $426,668 remaining on the award.

31. The Research Foundation on behalf of the University at Albany (UA) is a subrecipient to the University of Michigan on NIH Award Number 1R01AG082080-01A1, *Improving Inclusivity of Alzheimer's Disease and Related Dementias Research for Asian Americans and Latinx through Nationally Representative Hybrid Sampling."* The UA PI on the subaward is Dr. Elizabeth Vasquez. Director of the Center for the Elimination of Minority

Health Disparities at UA. The total amount of funding on the UA sub-award is $26,847. The total amount of the prime award to the University of Michigan for the period January 1, 2025, to December 31, 2025, is $1,072,668. The UA sub-award (including the University of Michigan prime award is attached hereto as Exhibit E.

32. The Research Foundation on behalf of SUNY Downstate Health Sciences University (Downstate) is a subrecipient to New York University on NIH Award Number 1RO1HL169503-01A1, *Geographically Explicit Ecological Momentary Assessment Protocol to Assess the Linkages between Intersectional Discrimination and CVD Risk Among Sexual and Gender Minorities.* The PI on the award is Dr. Jason Lazar, Executive Vice Dean and Chair of the Department of Medical Education, Downstate College of Medicine.

33. By letter of March 12, 2025, NIH summarily and without prior notice terminated Award 1P50MD019473-01 ("Murphy Termination Letter"). The Murphy Termination Letter is attached hereto as Exhibit F.

34. By letter of March 21,2025, NIH summarily terminated Project 5K01MH130270-03 ("Gyamerah Termination Letter") The Gyamerah Termination Letter is attached hereto as Exhibit G.

35. By letter of March 21, 2025, NIH summarily terminated Project R01AA028810-01A1 ("Hequenbourg Termination Letter"). The Hequenbourg Termination Letter is attached hereto as Exhibit H.

36. By email of March 21, 2025, the University of Michigan directed UA to stop work on the subaward because NIH summarily terminated Project 1R01AG082080-01A1 via an NIH letter of termination which was transmitted with the correspondence. ("Vasquez Termination Correspondence"). The Vasquez Termination Correspondence is attached hereto as Exhibit I.

37. By email of March 21, 2025, NYU directed Downstate to stop work on the subaward because NIH summarily terminated Project 1RO1HL169503-01A1 via a termination letter which was transmitted with the correspondence. ("Lazar Termination Correspondence"). The Lazar Termination Correspondence is attached hereto as Exhibit J.

38. The Murphy Termination Letter, the Gyamerah Termination Letter, and the Vasquez Termination Correspondence cite identical grounds for termination: "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans." The termination letter says nothing about why the project is a "DEI study" or how it is a "research program based primarily on artificial and non-scientific categories … that ultimately do[es] not enhance health, lengthen life, or reduce illness." Nor does it identify any alternative priorities that NIMHD or NIH now seeks to effectuate.

39. As stated in the Hequenbourg Termination Letter and the Lazar Termination Correspondence, the grounds for termination are: "This award no longer effectuates agency priorities. Research Programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." The Hequenbourg Termination Letter and the Lazar Termination Correspondence do not say why the award activities are considered an "unscientific gender identity research program" or why it "does nothing to enhance the health of

many Americans." I am aware that the Uniform Guidance in effect on the dates the dates the Murphy, Gyamerah and Hequenbourg grants were awarded (July 19, 2024; August 1, 2024; and July 1, 2024, respectively), provided in relevant part that a grant may be terminated "[b]y the Federal Awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities" 2. C.F.R. § 200.340(a)(2) (2023).

40. I am also familiar with the 2024 NIH Grants Policy Statement in effect on the dates of termination of the Murphy, Gyamerah and Hequenbourg Terminations, as cited in the Termination Letters, and with the regulations cited therein regarding the procedures applicable to termination of NIH awards (42 C.F.R. § 50.404) ("What disputes are covered by these procedures?")

41. The referenced procedures do not address termination of an award because it "no longer effectuate agency priorities" as stated in the March 12 termination letter despite the following provision of the Uniform Guidance in effect on July 19, 2024: "A federal awarding agency should clearly and unambiguously specify termination provisions applicable to each Federal award, in applicable regulations or in the award, consistent with this section" 2 C.F.R. § 200.340(b) (2023).

42. The Murphy, Gyamerah, and Hequenbourg Termination Letters also state: "although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

43. In my career as a senior research administrator at several research universities, I have never seen a summary termination of this nature without any ability to identify corrective action or program modifications to avoid suspension or termination. Nor do the procedures referenced in the termination letter provide any guidance whatsoever regarding how to challenge a termination for failing to effectuate unspecified agency priorities. I have no basis to identify the "issue(s) in dispute," to "provide a full statement of [our] position with respect to such issue(s)," or to supply "pertinent facts and reasons in support of [our] position."

Comparisons Across Administrations

44. Throughout my career in research administration, spanning 30 years, under both Democratic and Republican administrations, research universities have never experienced this volume of unexplained delays or procedural breakdowns.

45. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

Effect on Public-Facing or State-Supported Programs

46. Our institution administers multiple programs funded jointly by NIH and the State of New York, including community health clinics and research addressing health disparities. Delays in NIH funding have prevented the timely launch of a community health initiatives.

47. We are also unable to finalize contracts with other research partners until federal funds are secured.

Admissions, Training and Workforce Disruptions

48. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

Concerns About FY25 Funds Being Obligated

49. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

50. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of the award will occur in time.

Irreparable Harm

51. The delays have disrupted ongoing research, as well as setting back vital and impactful future research. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

52. Some of these studies had the potential to achieve significant breakthroughs which would have advanced

public health for the American public, and which will now not occur.

53. Delays have also disrupted community services, student opportunities, and public programs.

54. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

55. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

/s/Scott E Shurtleff
Scott E. Shurtleff

Date: April 1, 2025

Exhibit A to Shurtleff Declaration

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# P50MD019473
Federal Award Date
07/19/2024

Recipient Information

1. Recipient Name
RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK, THE
520 LEE ENTRANCE STE 211
AMHERST, NY 14228

2. Congressional District of Recipient
26

3. Payment System Identifier (ID)
1141368361A1

4. Employer Identification Number (EIN)
141368361

5. Data Universal Numbering System (DUNS)
038633251

6. Recipient's Unique Entity Identifier
LMCJKRFW5R81

7. Project Director or Principal Investigator
Timothy F Murphy, MD
Director
murphyt@buffalo.edu
(716) 881-8911

8. Authorized Official
Amy Lagowski

Federal Agency Information

9. Awarding Agency Contact Information
MICHELLE MAE Phillips
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
michelle.phillips@nih.gov
(301) 402-1366

10. Program Official Contact Information
Nathaniel Stinson
Director
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
stinsonn@mail.nih.gov
301-594-8704

Federal Award Information

11. Award Number
1P50MD019473-01

12. Unique Federal Award Identification Number (FAIN)
P50MD019473

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/19/2024 **– End Date** 01/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$724,502
20 a. Direct Cost Amount	$450,001
20 b. Indirect Cost Amount	$274,501
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$724,502
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$724,502
26. Project Period Start Date 07/19/2024 **– End Date** 01/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$724,502

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

SPECIALIZED RESEARCH CENTER
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 1P50MD019473-01

Principal Investigator(s):
Timothy F Murphy, MD

Award e-mailed to: awards@research.BUFFALO.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $724,502 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to SUNY Research Foundation in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number P50MD019473. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$83,847
Fringe Benefits	$46,352
Personnel Costs (Subtotal)	$130,199
Consultant Services	$29,400
Travel	$1,350
Other	$19,052
Participant Other	$270,000
Federal Direct Costs	$450,001
Federal F&A Costs	$274,501
Approved Budget	$724,502
Total Amount of Federal Funds Authorized (Federal Share)	$724,502
TOTAL FEDERAL AWARD AMOUNT	$724,502
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$724,502

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$724,502	$724,502
2	$723,103	$723,103
3	$717,902	$717,902
4	$716,233	$716,233
5	$714,523	$714,523

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1141368361A1
Document Number:	PMD019473A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027	2028
MD	8067679	$724,502	$723,103	$717,902	$716,233	$714,523

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CPS01 / **OC**: 41021 / **Released**: 07/12/2024
Award Processed: 07/19/2024 12:19:02 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P50MD019473-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P50MD019473-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

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references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P50MD019473. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

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- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 1P50MD019473-01

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION This award is issued without a currently valid certification of IRB approval for this project with the following special condition: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46 and certification of IRB approval has been submitted to and accepted by the NIMHD.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by both (1) the recipient's OHRP-approved Assurance and if performance sites are involved, each performance site's OHRP-approved Assurance(s) and (2) appropriate IRB approvals consistent with all OHRP-approved Assurances.

Failure to comply with this special condition can result in the suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

RESTRICTION This award is issued subject to the following special condition:

In accordance with NIH policy, no research involving human subjects may be conducted on this project until the NIMHD receives certification that all key personnel as defined in the June 5, 2000 NIH Guide announcement, (revised August 25, 2000), "Required Education in the Protection of Human Subjects" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html), have completed education on the protection of human subjects; and the NIMHD removes this restriction. The certification(s) for key personnel involved in this project, clearly identifying the grant number, must be sent no later than November 1,

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2024 to pg38h@nih.gov and the assigned Grants Management Specialist.

If the certification(s) is not received by the date listed above, this award may be suspended and may be terminated. The award also may be subject to audit disallowances and/or other appropriate action.

REQUIREMENT This award is subject to the conditions set forth in RFA-MD-23-011, NIMHD Centers of Excellence in Investigator Development and Community Engagement (P50 - Clinical Trial Optional), NIH Guide to Grants and Contracts, May 24, 2023, which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address:

RFA-MD-23-011: NIMHD Centers of Excellence in Investigator Development and Community Engagement (P50 - Clinical Trial Optional) (nih.gov)

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

RESTRICTION This award is made for the purpose of assisting the recipient in supporting a program of excellence as set forth in Public Law 106-525, Title I, Sec. 102 (https://www.congress.gov/bill/106th-congress/senate-bill/1880/text?overview=closed). Funds must be expended in accordance with this Act's purpose and requirements.

The pilot project program is expected to support the biomedical and behavioral research training and professional development of researchers who are members of health disparity populations. Eligibility to receive a pilot project award is limited to the post-doctoral fellows, junior faculty and other early stage investigators as defined by NIH (see https://grants.nih.gov/policy/new_investigators/index.htm#definition) of the recipient institution and collaborating/consortium **institutions which would have been eligible to apply* for a COE award under RFA-MD-23-011 (**where eligible pilot individuals are primarily employed/enrolled/affiliated long-term (without temporarily changing their employment/enrollment/affiliation status for this purpose)]. Recruitment of investigators from groups underrepresented in science (http://www.nsf.gov/statistics/wmpd/) is encouraged.

> * Pursuant to Public Law 106-525, institutions of higher education must meet the following criteria to be eligible: (A) Has a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution). NIH-designated health disparity populations are Black/African Americans, American Indians or Alaska Natives, Asian Americans, Hispanics or Latinos, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities. (B) Has been effective in assisting such students of the institution to complete the

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program of education or training and receive the degree involved. (C) Has made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate. (D) Has made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution. **Note**: NIH-designated populations that experience health disparities are Black/African Americans, American Indians or Alaska Natives, Asian Americans, Hispanics or Latinos, Native Hawaiians and other Pacific Islanders, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities.

RESTRICTION The pilot project program is expected to support the training and professional development of researchers who are members of health disparity populations. Eligibility to receive a pilot project award is limited to the recipient institution's post-doctoral fellows, junior faculty and other early stage investigators as defined by NIH
(see https://grants.nih.gov/policy/new_investigators/index.htm#definition). Pilot project award eligibility refers to where these employees/students/trainees are primarily employed/enrolled/affiliated long-term (e.g., without temporarily changing their employment/enrollment/affiliation status for this purpose). Recruitment of early career investigators from groups underrepresented in science http://www.nsf.gov/statistics/wmpd/) is strongly encouraged.

REQUIREMENT **Annual funding for the pilot project program must be a minimum of $300,000 total direct costs (including consortium indirect costs) with at least three new pilot projects awarded each year** (typically beginning in year 2). Pilot project applications should use the current SF 424 (R&R) application forms package for NIH R03 small grant applications.

RESTRICTION Projects using live vertebrate animals cannot be supported under the Pilot Project Program.

REQUIREMENT The recipient is required to follow the guidance in NOT-OD-15-128, “Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice,” and NOT-OD-15-129, “Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice” in the approval of pilot projects, which are hereby incorporated by reference as special terms and conditions of this award.

(1) For “minimal risk” human subjects activities, the recipient will conduct the review and selection of these pilots, as well as ensure IRB approval and compliance with all Federal rules, regulations, and policies regarding human subjects research. For documentation/awareness, the recipient’s AOR must email the following information to pg38h@nih.gov and the assigned Grants

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Management Specialist at the time of approval and include a copy in the next RPPR or progress report: the grant number, contact PI name, approval date, pilot title, pilot PI name, pilot PI biosketch, a one sentence pilot project summary, a copy of the IRB approval, Inclusion Enrollment Record (IER) submitted to the NIH Human Subjects System (HSS), and the AOR's attestation that they followed applicable Federal rules, regulations, and policies.

(2) For human subjects activities that involve greater than minimal risk, the recipient's AOR will email prior approval requests to pg38h@nih.gov and the assigned Grants Management Specialist or submit them online using the eRA prior approval system, following this process: NIMHD prior approval in a revised Notice of Award must be received prior to starting any new research involving human subjects that involve greater than minimal risk. The recipient will submit to NIH via the HSS system, study protocols that address risks and protections for human subjects in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan and specific plans for data and safety monitoring, IRB approval and FWA, and email a copy to pg38h@nih.gov and the assigned Grants Management Specialist.

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

REQUIREMENT With respect to authorized activities, the institution, or institutions in the consortium, as the case may be, must agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the institutions involved for the fiscal year preceding the fiscal year for which such institutions receive such an award. With respect to any Federal amounts received by the Center or consortium and available for carrying out authorized activities, the institutions involved agree that the institutions will, before expending the award, expend the Federal amounts obtained from sources other than the award.

INFORMATION In accordance with the National Institute on Minority Health and Health Disparities' (NIMHD's) Fiscal Year (FY) 2024 funding policies, this award has been issued at 90%of the corrected recommended level. Future year committed levels* have been adjusted accordingly.

* committed level. The level of support calculated by applying the NIMHD funding plan to the corrected recommended level for each budget category for all years of the project period.

INFORMATION In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with a shortened budget period and with 12 months of support. Continuation awards will cycle each year on February 1.

INFORMATION Although the budget period start date for this award is 7/19/2024, this award includes funds for 12 months of support. Future year

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budget periods will cycle on February 1. Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, and with institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

INFORMATION Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P50MD019473-01

INSTITUTION: SUNY Research Foundation

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$83,847	$84,432	$83,846	$83,846	$83,846
Fringe Benefits	$46,352	$46,740	$46,352	$46,352	$46,352
Personnel Costs (Subtotal)	$130,199	$131,172	$130,198	$130,198	$130,198
Consultant Services	$29,400	$29,400	$29,400	$29,400	$29,400
Travel	$1,350	$1,350	$1,350	$1,350	$1,350
Other	$19,052	$17,210	$14,954	$13,917	$12,855
Participant Other	$270,000	$270,000	$270,000	$270,000	$270,000
TOTAL FEDERAL DC	$450,001	$449,132	$445,902	$444,865	$443,803
TOTAL FEDERAL F&A	$274,501	$273,971	$272,000	$271,368	$270,720
TOTAL COST	$724,502	$723,103	$717,902	$716,233	$714,523

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	61%	61%	61%	61%	61%
F&A Cost Base 1	$450,001	$449,132	$445,902	$444,865	$443,803
F&A Costs 1	$274,501	$273,971	$272,000	$271,368	$270,720

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Exhibit B to Shurtleff Declaration

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Mental Health (NIMH)
Funding Opportunity Title	Research Project Grant (Parent R01 Clinical Trial Required)
Activity Code	R01
Announcement Type	New
Related Notices	▪ October 24, 2025 - Re-issuance: PA-26-004 to Clarify Application Instructions Effective for Due Dates On or After January 25, 2026 ▪ October 24, 2025 - Re-issuance: PA-26-005 to Clarify Application Instructions Effective for Due Dates On or After January 25, 2026 ▪ June 18, 2025 - Publication of PA-25-305 ▪ June 18, 2025 - Publication of PA-25-306 ▪ June 18, 2025 - Publication of PA-25-307 ▪ June 18, 2025 - Publication of PA-25-308 ▪ June 18, 2025 - Publication of PA-25-309 ▪ June 18, 2025 - Publication of

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

Component Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the inclusion of the clinical trial may indicate that further clinical development of the intervention is unsupported or that is new and/or scientific investigation.

Additional Review Criteria: Overall

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessments? Is the proposed timeline feasible and well justified? Does the project incorporate effectiveness and other existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justification for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if AVMA guidelines are not followed. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations - Overall

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Review Criteria - Cores

Reviewers will consider each of the review criteria below in the determination of scientific merit.

Review Criteria - Administrative Core

- Is an appropriate Management Plan provided describing the Center's organizational and governance structure, including any advisory committees, and strategies for overseeing, managing and coordinating the entire range of proposed Center activities?
- Are the proposed administrative processes adequate to ensure the timely completion of the projects that component plans are implemented?
- Are the roles and responsibilities of each personnel clearly delineated and appropriate?
- Are there adequate institutional plans and procedures to assure compliance with applicable federal regulations and NIH policies for the protection of human research participants, including the evaluation of risks and protections in project proposals, appropriate ethical oversight of funded projects, and plans for monitoring data and safety in clinical research projects?
- Is there a well-conceived and justified Bud incorporates appropriate performance targets, objectives, and outcomes?
- Are the roles of the Advisory Board and/or other committees clearly delineated and appropriate, if applicable?

Review Criteria - Investigator-Development Core

- How likely is the proposed Pilot Project Program to promote and enhance career development and transition to independence for post-doctoral fellows, junior faculty and other early stage investigators, including those from diverse backgrounds, to establish productive, independent research careers?
- Are criteria and procedures for soliciting, submitting, reviewing and selecting pilot projects for funding, including the expected number, distribution, direct costs and duration of pilot projects, clearly described and adequately justified in the overall context of the Center's proposed objectives?
- Are appropriate administrative and technical support resources in place to support rigorous research design, appropriate statistical analyses, and compliance with applicable Federal regulations and NIH policies for the protection of human research participants and vertebrate animals?
- To what extent are plans for overseeing and mentoring pilot awardees, including commitment of the identified mentors, likely to enhance their professional development?

Review Criteria - Community Engagement and Dissemination Core

- To what extent are the proposed activities likely to successfully establish or enhance sustainable partnerships with community-based organizations and community members to address their health-related concerns and promote participation in the Center's research activities?
- Are plans for dissemination of information to a broad range of audiences well described and consistent with the objectives of the Center?
- Are plans to engage in strategic planning processes to translate findings into sustainable community and system level changes at the local level and beyond described and realistic?
- Are the leadership, policies and practices clearly and appropriately described?

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIAMS, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned a priority score.

Appeals of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council on Minority Health and Health Disparities.

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Geographic distribution of awardees.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PI/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section III.3, Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application received in response to the NOFO will be subject to the terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the 22 specific terms and conditions identified in the NoA.

Clinical Trials.gov: If an award provides for one or more clinical trials, By law (Title VIII, Section 801 of Public Law 110-85, title "responsible party" must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System information Website (https://register.clinicaltrials.gov). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm.

Institutional Review Board or Independent Ethics Committee Approval: Grantee institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in the trial, the IRB or IEC must review the relevant data and safety information at least annually. See 45 CFR 46.109(e).

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Prior Approval of Pilot Projects

Recipient-selected projects that involve: greater than minimal risk to human subjects require prior approval by NIH prior to initiation.

- The recipient institution will comply with the NIH Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval.
- The recipient institution will submit to NIH specific plans for data and safety monitoring, and will notify the IRB and NIH of serious adverse events and unanticipated problems involving risks to subjects or others.
- Projects using fast-verification animals cannot be supported under the Pilot Project Program.

2. Administration and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including but not limited to:

- Federal-wide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgement of Federal Funding

For recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Departments regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a condition of receiving the grant, to administer programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes the requirement to provide services in accessible formats and to ensure effective communication with persons in languages other than English and with persons with disabilities. Where applicable, Title IX and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-individuals/index.html and https://www.hhs.gov/civil-rights/for-providers/index.html for more information.

HHS recognizes that research projects are described in detail in the funded research that are methodologically, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the NIH awarding component information listed in the NoA or see the publication.

- For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/clear-mail-ensuring-access-programs/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and/or provide effective communications, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/policy/publicity/harassment.htm.
- For guidance on publication and publicity requirements, see Publication and Publicity. For guidance on publication and publicity requirements, see https://www.hhs.gov/civil-rights/for-providers/provider-conscience/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award-making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal awarding agency previously entered and is currently in FAPIIS. The designated integrity and performance system will be accessible through the System for Award Management (SAM), which is the Government-wide system that Federal awarding agencies, and awardees shall use to disclose information required by the applicant, in addition to other information in FAPIIS. In making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing Plan submitted and approved as part of the application. Privacy Act Statement: Not Applicable. Failure to submit a Data Management and Sharing Plan, if required for recipients to implement the plan via attachment. If additional Data Management and Sharing requirements need to be added, please check what requirements are desired.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

Progress reports should briefly describe status of pilot projects, including data and safety monitoring, and should notify NIH of serious adverse events and stand-pulsed problems.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. NIH publication of publicly accessible Publication Publication Terms. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.342 and 2 CFR Part 200.334.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2010 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.0 Part 200.213 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, which is the period of performance plus 1 year, must report and maintain the currency of information reported in the System for Award Management about any civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement implemented in 2 CFR Part 200, Appendix XII, 2 CFR Part 200.113 and 2 CFR Part 200.340. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part Tland 2 CFR Part 200 - Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-627-3940

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Telephone: 800-518-4726 or 606-545-5035
Email: support@grants.gov

Scientific/Research Contact(s)
Nathan Stinson Jr., PhD, MD, MPH
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-827-4388
Email: nathaniel.stinson@nih.gov

Peer Review Contact(s)
Ross D. Shonat, PhD
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-827-7818
Email: ross.shonat@nih.gov

Financial/Grants Management Contact(s)
Priscilla Grant, JD
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-827-2412
Email: pg89@nih.gov

Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Publication Publication Publication of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Notice: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.

Exhibit C to Shurtleff Declaration

PI: **Murphy, Timothy F**	Title: Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers	
Received: 08/04/2023	Opportunity: RFA-MD-23-011	Council: 01/2024
Competition ID: FORMS-H	FOA Title: NIMHD Centers of Excellence in Investigator Development and Community Engagement (P50 - Clinical Trial Optional)	
1P50MD019473-01	Dual:	Accession Number: 4864707
IPF: 5992614	Organization: STATE UNIVERSITY OF NEW YORK AT BUFFALO	
Former Number:	Department:	
IRG/SRG: ZMD1 MLS (J1)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 499,999 Year 2: 499,998 Year 3: 500,003 Year 4: 500,001 Year 5: 499,999	Animals: N Humans: Y Clinical Trial: Y Current HS Code: 30 HESC: N HFT: N Special Topics: Data Management Sharing	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Timothy Murphy M.D.	STATE UNIVERSITY OF NEW YORK AT BUFFALO	PD/PI
Susan Grinslade Ph.D	SUNY at Buffalo	Co-Investigator
Ekaterina Noyes Ph.D	SUNY at Buffalo	Co-Investigator
Henry Taylor Ph.D	SUNY at Buffalo	Co-Investigator
Gregory Wilding Ph.D	SUNY at Buffalo	Co-Investigator
Robert Silverman Ph.D	SUNY at Buffalo	Co-Investigator
Christopher St. Vil Ph.D	SUNY at Buffalo	Co-Investigator
Oscar Gómez Ph.D	SUNY at Buffalo	Co-Investigator
Heather Orom Ph.D	SUNY at Buffalo	Co-Investigator
Kinzer Pointer	Concerned Clergy Coalition of Western New York	Other (Specify)-Collaborator
Carol Van Zile Tamsen Ph.D	SUNY at Buffalo	Other (Specify)-Evaluator

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier** New York

1. TYPE OF SUBMISSION*

○ Pre-application ○ Application ● Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number GRANT13949934

5. APPLICANT INFORMATION **UEI*:** LMCJKRFW5R81

Legal Name*: The Research Foundation for SUNY on behalf of U. at Buffalo
Department: Sponsored Projects Services
Division:
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567

Person to be contacted on matters involving this application
Prefix: First Name*: Amy Middle Name: Last Name*: Lagowski Suffix:
Position/Title: Agreement Administartor
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567
Phone Number*: 716-645-4419 Fax Number: Email: amy.lagowski@buffalo.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1-141368361-A1

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): Private, Non-Profit
Small Business Organization Type ○ Women Owned ○ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ○ Resubmission
○ Renewal ○ Continuation ○ Revision

If Revision, mark appropriate box(es).

○ A. Increase Award ○ B. Decrease Award ○ C. Increase Duration
○ D. Decrease Duration ○ E. Other *(specify)* :

Is this application being submitted to other agencies?* ○Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers

12. PROPOSED PROJECT
Start Date* Ending Date*
04/01/2024 03/31/2029

13. CONGRESSIONAL DISTRICTS OF APPLICANT
NY-026

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Timothy Middle Name: Last Name*: Murphy Suffix: M.D.
Position/Title:
Organization Name*: STATE UNIVERSITY OF NEW YORK AT BUFFALO
Department:
Division:
Street1*: 875 Ellicott St.
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14203-1034
Phone Number*: (716) 881-8911 Fax Number: Email*: murphyt@buffalo.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$4,025,000.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$4,025,000.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Amy Middle Name: Last Name*: Lagowski Suffix:
Position/Title*: Agreement Administrator
Organization Name*: The Research Foundation for SUNY on behalf of U. at Buffalo
Department: Sponsored Projects Services
Division:
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567
Phone Number*: 716-645-4419 Fax Number: Email*: amy.lagowski@buffalo.edu

Signature of Authorized Representative*
Amy Lagowski

Date Signed*
08/04/2023

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

424 R&R and PHS-398 Specific
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Component Summary

Components	Component Project Title	Organization Name	Contact PD/PI Name or Project Lead Name
Overall	Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers	The Research Foundation for SUNY on behalf of U. at Buffalo	Murphy, Timothy
Admin-Core-001 (344)	Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers	The Research Foundation for SUNY on behalf of U. at Buffalo	Murphy, Timothy
Core-001 (154)	Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers	The Research Foundation for SUNY on behalf of U. at Buffalo	Silverman, Robert
Investigator-Core-001 (358)	Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers	The Research Foundation for SUNY on behalf of U. at Buffalo	Gómez, Oscar

Project/Performance Site Location(s) Summary

Applicant Organization	City	State/Province	Country
The Research Foundation for SUNY on behalf of U. at Buffalo	Amherst	NY	UNITED STATES

Organization Name	City	State/Province	Country	Component
Buffalo Center for Health Equity	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
Buffalo Center for Health Equity	Buffalo	NY	UNITED STATES	Core-001 (154)
Buffalo Center for Health Equity	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
Buffalo Center for Health Equity	Buffalo	NY	UNITED STATES	Overall
The Research Foundation for SUNY on behalf of U. at Buffalo	Amherst	NY	UNITED STATES	Admin-Core-001 (344)
The Research Foundation for SUNY on behalf of U. at Buffalo	Amherst	NY	UNITED STATES	Core-001 (154)
The Research Foundation for SUNY on behalf of U. at Buffalo	Amherst	NY	UNITED STATES	Investigator-Core-001 (358)
The Research Foundation for SUNY on behalf of U. at Buffalo	Amherst	NY	UNITED STATES	Overall
UB Clinical and Translational Research Center	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB Clinical and Translational Research Center	Buffalo	NY	UNITED STATES	Core-001 (154)
UB Clinical and Translational Research Center	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB Clinical and Translational Research Center	Buffalo	NY	UNITED STATES	Overall
UB Community Health Equity Research Institute	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB Community Health Equity Research Institute	Buffalo	NY	UNITED STATES	Core-001 (154)
UB Community Health Equity Research Institute	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB Community Health Equity Research Institute	Buffalo	NY	UNITED STATES	Overall
UB Jacobs School of Medicine and Biomedical Sciences	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB Jacobs School of Medicine and Biomedical Sciences	Buffalo	NY	UNITED STATES	Core-001 (154)

UB Jacobs School of Medicine and Biomedical Sciences	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB Jacobs School of Medicine and Biomedical Sciences	Buffalo	NY	UNITED STATES	Overall
UB School of Architecture and Planning	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB School of Architecture and Planning	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB School of Architecture and Planning	Buffalo	NY	UNITED STATES	Overall
UB School of Architecture and Plannning	Buffalo	NY	UNITED STATES	Core-001 (154)
UB School of Nursing	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB School of Nursing	Buffalo	NY	UNITED STATES	Core-001 (154)
UB School of Nursing	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB School of Nursing	Buffalo	NY	UNITED STATES	Overall
UB School of Public Health and Health Professions	Buffalo	NY	UNITED STATES	Admin-Core-001 (344)
UB School of Public Health and Health Professions	Buffalo	NY	UNITED STATES	Core-001 (154)
UB School of Public Health and Health Professions	Buffalo	NY	UNITED STATES	Investigator-Core-001 (358)
UB School of Public Health and Health Professions	Buffalo	NY	UNITED STATES	Overall

Human Subjects
Clinical Trials
Vertebrate Animals
HESC
Human Fetal Tissue
Summary

Component	Human Subjects	Clinical Trial / Anticipated Clinical Trial	Vertebrate Animals	HESC	Human Fetal Tissue
Overall	Y	N	N	N	N
Admin-Core-001 (344)	N	N	N	N	N
Core-001 (154)	N	N	N	N	N
Investigator-Core-001 (358)	Y	Y	N	N	N

Study Summary

Component	Study	Delayed Onset	Clinical Trial/Anticipated Clinical Trial	NIH Defined Phase III Clinical Trial
Investigator-Core-001 (358)	TBD Based on Pilot Study Selections	Yes	Yes	

Composite Application Budget Summary

Categories	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Salary, Wages and Fringe Benefits	144,663	146,709	149,221	150,371	151,549	742,513
Equipment	0	0	0	0	0	0
Travel	1,500	1,500	1,500	1,500	1,500	7,500
Participant/Trainee Support Costs	300,000	300,000	300,000	300,000	300,000	1,500,000
Data Management and Sharing (DMS) Costs*	0	0	0	0	0	0
Human Fetal Tissue (HFT) Costs*						0
Other Direct Costs (excluding Consortium)	53,836	51,789	49,282	48,130	46,950	249,987
Consortium Costs	0	0	0	0	0	0
Direct Costs	499,999	499,998	500,003	500,001	499,999	2,500,000
Indirect Costs	305,001	304,999	305,002	305,000	304,998	1,525,000
Total Direct and Indirect Costs	805,000	804,997	805,005	805,001	804,997	**4,025,000**

*HFT/DMS Costs, if present, are included in the budget summary for information only; the values have not been subtracted from "Other Direct Costs (excluding Consortium)"

Total Direct Costs less Consortium F&A

NIH policy (NOT-OD-05-004) allows applicants to exclude consortium/contractual F&A costs when determining if an application falls at or beneath any applicable direct cost limit. When a direct cost limit is specified in an FOA, the following table can be used to determine if your application falls within that limit.

Category	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Total Direct Costs less Consortium F&A	499,999	499,998	500,003	500,001	499,999	**2,500,000**

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Component Budget Summary

Components	Categories	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Admin-Core-001 (344)	Salary, Wages and Fringe Benefits	66,327	67,581	69,207	70,173	71,160	344,448
	Equipment	0	0	0	0	0	0
	Travel	1,500	1,500	1,500	1,500	1,500	7,500
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Data Management and Sharing Costs*	0	0	0	0	0	0
	Human Fetal Tissue Costs*						0
	Other Direct Costs (excluding Consortium)	18,667	18,667	18,667	18,667	18,667	93,335
	Consortium Costs	0	0	0	0	0	0
	Direct Costs	86,494	87,748	89,374	90,340	91,327	445,283
	Indirect Costs	52,761	53,526	54,518	55,107	55,709	271,621
TOTALS	Total Direct and Indirect Costs	139,255	141,274	143,892	145,447	147,036	**716,904**
Core-001 (154)	Salary, Wages and Fringe Benefits	37,365	37,678	38,005	38,005	38,005	189,058
	Equipment	0	0	0	0	0	0
	Travel	0	0	0	0	0	0
	Participant/Trainee Support Costs	0	0	0	0	0	0
	Data Management and Sharing Costs*						0
	Human Fetal Tissue Costs*						0
	Other Direct Costs (excluding Consortium)	24,000	24,000	24,000	24,000	24,000	120,000

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	Consortium Costs	0	0	0	0	0	0
	Direct Costs	61,365	61,678	62,005	62,005	62,005	309,058
	Indirect Costs	37,434	37,624	37,823	37,823	37,823	188,527
TOTALS	Total Direct and Indirect Costs	98,799	99,302	99,828	99,828	99,828	**497,585**
Investigator-Core-001 (358)	Salary, Wages and Fringe Benefits	40,971	41,450	42,009	42,193	42,384	209,007
	Equipment	0	0	0	0	0	0
	Travel	0	0	0	0	0	0
	Participant/Trainee Support Costs	300,000	300,000	300,000	300,000	300,000	1,500,000
	Data Management and Sharing Costs*						0
	Human Fetal Tissue Costs*						0
	Other Direct Costs (excluding Consortium)	11,169	9,122	6,615	5,463	4,283	36,652
	Consortium Costs	0	0	0	0	0	0
	Direct Costs	352,140	350,572	348,624	347,656	346,667	1,745,659
	Indirect Costs	214,806	213,849	212,661	212,070	211,466	1,064,852
TOTALS	Total Direct and Indirect Costs	566,946	564,421	561,285	559,726	558,133	**2,810,511**
TOTALS		**805,000**	**804,997**	**805,005**	**805,001**	**804,997**	**4,025,000**

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Categories Budget Summary

Categories	Components	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
R&R Budget - Senior/Key Person Funds Requested	Admin-Core-001 (344)	66,327	67,581	69,207	70,173	71,160	344,448
	Core-001 (154)	37,365	37,678	38,005	38,005	38,005	189,058
	Investigator-Core-001 (358)	40,971	41,450	42,009	42,193	42,384	209,007
TOTALS		144,663	146,709	149,221	150,371	151,549	**742,513**
R&R Budget - Other Personnel Funds Requested	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Section A & B. Total Salary, Wages and Fringe Benefits (A+B)	Admin-Core-001 (344)	66,327	67,581	69,207	70,173	71,160	344,448
	Core-001 (154)	37,365	37,678	38,005	38,005	38,005	189,058
	Investigator-Core-001 (358)	40,971	41,450	42,009	42,193	42,384	209,007
TOTALS		144,663	146,709	149,221	150,371	151,549	**742,513**
R&R Budget - Section C. Total Equipment	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**

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R&R Budget - Domestic Travel	Admin-Core-001 (344)	1,500	1,500	1,500	1,500	1,500	7,500
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		1,500	1,500	1,500	1,500	1,500	**7,500**
R&R Budget - Foreign Travel	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Section D. Total Travel	Admin-Core-001 (344)	1,500	1,500	1,500	1,500	1,500	7,500
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		1,500	1,500	1,500	1,500	1,500	**7,500**
R&R Budget - Tuition/Fees/Health Insurance	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Stipends	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0

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TOTALS		0	0	0	0	0	**0**
R&R Budget - Trainee Travel	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Subsistence	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Participants/Trainee Support Costs	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	300,000	300,000	300,000	300,000	300,000	1,500,000
TOTALS		300,000	300,000	300,000	300,000	300,000	**1,500,000**
R&R Budget - Section E. Total Participants/Trainee Support Costs	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	300,000	300,000	300,000	300,000	300,000	1,500,000
TOTALS		300,000	300,000	300,000	300,000	300,000	**1,500,000**
R&R Budget - Materials and Supplies	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0

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	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Publication Costs	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Consultant Services	Admin-Core-001 (344)	18,667	18,667	18,667	18,667	18,667	93,335
	Core-001 (154)	14,000	14,000	14,000	14,000	14,000	70,000
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		32,667	32,667	32,667	32,667	32,667	**163,335**
R&R Budget - ADP/Computer Services	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Subawards/Consortium/Contractual Costs	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Equipment or Facility	Admin-Core-001	0	0	0	0	0	0

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Rental User Fees	(344)						
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Alterations and Renovations	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 1	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	10,000	10,000	10,000	10,000	10,000	50,000
	Investigator-Core-001 (358)	11,169	9,122	6,615	5,463	4,283	36,652
TOTALS		21,169	19,122	16,615	15,463	14,283	**86,652**
R&R Budget - Other Direct Cost 2	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 3	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0

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TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 4	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 5	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 6	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 7	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 8	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0

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	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 9	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Other Direct Cost 10	Admin-Core-001 (344)	0	0	0	0	0	0
	Core-001 (154)	0	0	0	0	0	0
	Investigator-Core-001 (358)	0	0	0	0	0	0
TOTALS		0	0	0	0	0	**0**
R&R Budget - Section F. Total Other Direct Cost	Admin-Core-001 (344)	18,667	18,667	18,667	18,667	18,667	93,335
	Core-001 (154)	24,000	24,000	24,000	24,000	24,000	120,000
	Investigator-Core-001 (358)	11,169	9,122	6,615	5,463	4,283	36,652
TOTALS		53,836	51,789	49,282	48,130	46,950	**249,987**
R&R Budget - Section G. Total Direct Cost (A thru F)	Admin-Core-001 (344)	86,494	87,748	89,374	90,340	91,327	445,283
	Core-001 (154)	61,365	61,678	62,005	62,005	62,005	309,058
	Investigator-Core-001 (358)	352,140	350,572	348,624	347,656	346,667	1,745,659
TOTALS		499,999	499,998	500,003	500,001	499,999	**2,500,000**
R&R Budget - Section H. Indirect Costs	Admin-Core-001 (344)	52,761	53,526	54,518	55,107	55,709	271,621

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	Core-001 (154)	37,434	37,624	37,823	37,823	37,823	188,527
	Investigator-Core-001 (358)	214,806	213,849	212,661	212,070	211,466	1,064,852
TOTALS		305,001	304,999	305,002	305,000	304,998	**1,525,000**
R&R Budget - Section I. Total Direct and Indirect Costs (G +H)	Admin-Core-001 (344)	139,255	141,274	143,892	145,447	147,036	716,904
	Core-001 (154)	98,799	99,302	99,828	99,828	99,828	497,585
	Investigator-Core-001 (358)	566,946	564,421	561,285	559,726	558,133	2,810,511
TOTALS		805,000	804,997	805,005	805,001	804,997	**4,025,000**

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Senior/Key Personnel
Summary

Name	Organization	Role on Project	Components
Murphy, Timothy	STATE UNIVERSITY OF NEW YORK AT BUFFALO	PD/PI(Contact)	Overall
Grinslade, Susan	SUNY at Buffalo	Co-Investigator	Core-001 (154)
Grinslade, Susan	SUNY at Buffalo	Co-Investigator	Overall
Gómez, Oscar	SUNY at Buffalo	Co-Investigator(Contact)	Investigator-Core-001 (358)
Gómez, Oscar	SUNY at Buffalo	Co-Investigator	Overall
Murphy, Timothy	STATE UNIVERSITY OF NEW YORK AT BUFFALO	Other: Admin Core Director	Admin-Core-001 (344)
Noyes, Ekaterina	SUNY at Buffalo	Co-Investigator	Investigator-Core-001 (358)
Noyes, Ekaterina	SUNY at Buffalo	Co-Investigator	Overall
Orom, Heather	SUNY at Buffalo	Co-Investigator	Core-001 (154)
Orom, Heather	SUNY at Buffalo	Co-Investigator	Overall
Pointer, Kinzer	Concerned Clergy Coalition of Western New York	Other: Co-Director of Investigator Dev. Core	Investigator-Core-001 (358)
Pointer, Kinzer	Concerned Clergy Coalition of Western New York	Other: Collaborator	Overall
Silverman, Robert	SUNY at Buffalo	Co-Investigator(Contact)	Core-001 (154)
Silverman, Robert	SUNY at Buffalo	Co-Investigator	Overall
St. Vil, Christopher	SUNY at Buffalo	Co-Investigator	Core-001 (154)
St. Vil, Christopher	SUNY at Buffalo	Co-Investigator	Overall
Taylor, Henry Louis	SUNY at Buffalo	Co-Investigator	Core-001 (154)
Taylor, Henry Louis	SUNY at Buffalo	Co-Investigator	Investigator-Core-001 (358)
Taylor, Henry Louis	SUNY at Buffalo	Co-Investigator	Overall
Van Zile Tamsen, Carol	SUNY at Buffalo	Other: Evaluator	Admin-Core-001 (344)
Van Zile Tamsen, Carol	SUNY at Buffalo	Other: Evaluator	Overall
Wilding, Gregory	SUNY at Buffalo	Co-Investigator	Investigator-Core-001 (358)
Wilding, Gregory	SUNY at Buffalo	Co-Investigator	Overall

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BIOGRAPHICAL SKETCH

NAME: Murphy, Timothy F. MD

eRA COMMONS USER NAME (credential, e.g., agency login): tmurphy

POSITION TITLE: SUNY Distinguished Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
New York University, New York, NY	BS	05/1972	Biology
Tufts University, Boston, MA	MD	06/1976	Medicine
Cornell University, New York	Residency	06/1979	Internal Medicine
Tuffs University, Boston, MA	Fellowship	06/1981	Infectious Disease

A. Personal Statement

My experience as a physician scientist, a mentor and an institutional leader has prepared me well to serve as PI of this proposal for an NIMHD Center of Excellence in Investigator Development and Community Engagement.

I have a passion and a long-term commitment to training future scientists. I have had the opportunity to mentor high school students, undergraduate college students, medical students, masters level graduate students, Ph.D. graduate students, medical residents, M.D. infectious diseases fellows, M.D. pulmonary fellows, and Ph.D. postdoctoral fellows in my laboratory. I have mentored junior faculty members supported by K awards and other similar mechanisms. Fourteen graduate students in microbiology have earned PhDs in my lab, including three MD-PhD students.

In addition to mentoring trainees, I have a strong commitment to training program administration. I am currently PI of a T35 training grant from NIAID, “Training the Next Generation of Clinician Scientists.” Over the first 10 years of this program 37% of trainees were from groups underrepresented in medicine and 62% were women. Previously, I served as Program Director of the ACGME-certified Infectious Diseases Fellowship Program at UB from 1993 through 2000.

As Principal Investigator of the University at Buffalo Clinical and Translational Science Award (CTSA), I serve as Director of the University at Buffalo Clinical and Translational Science Institute (CTSI). The mission of the Institute is to advance and accelerate innovative clinical and translational research to reduce health disparities and improve the health of our community and the nation. All of the extensive resources and services of the CTSI will be available to support the early career investigators supported by this proposal.

In 2019, UB launched the UB Community Health Equity Research Institute that conducts research that addresses the root causes of health disparities, while developing and testing innovative solutions to eliminate health inequities in the region. I am privileged to serve as Director of the Institute, which includes faculty from twelve UB schools and works closely with community partners. The mission of the CTSI and the community partnerships that developed as a result were critical in the “birth” of the Community Health Equity Research Institute.

My scientific interests focus on the respiratory tract bacterial pathogens nontypeable *Haemophilus influenzae* and *Moraxella catarrhalis*, including the molecular epidemiology of infection, mechanisms of pathogenesis and vaccine development. This work has been continuously funded by the NIH since 1983. My work has also included conducting a 20-year prospective, observational study of bacterial infection in adults with COPD from 1994 to 2014 that has generated an enormously valuable repository of data, bacterial strains, serum and sputum samples. My current work focuses on 2 areas. 1) Analysis of the genomes of several hundred strains of *H. influenzae* and *M. catarrhalis* collected in our prospective study of COPD to elucidate mechanisms of persistence in the airways of adults with COPD. 2) Prevention of bacterial otitis media in children and bacterial infection in

COPD through vaccine development for nontypeable *H. influenzae* and *M. catarrhalis*. Both COPD and otitis media (ear infections) disproportionately affect and impact populations that experience health disparities.

Ongoing funded projects that I would like to highlight include:
Award Number: UL1 TR001412
Sponsor: NIH/NCATS
PI: Murphy, Timothy
Award Dates: 08/15/15-12/31/24
Project Title: University at Buffalo Clinical and Translational Science Institute

Award Number: R01 AI19641
Sponsor: NIH/NIAID
PI: Murphy, Timothy
Award Dates: 09/01/83-06/30/24
Project Title: Genome Evolution During Bacterial Persistence in the Human Airways in COPD

Award Number: R13 TR003486
Sponsor: NIH/NCATS
PI: Murphy, Timothy
Award Dates: 07/01/20-06/30/23 NCE 7-1-23- 6/30/24
Project Title: Igniting Hope: Mobilizing Community Resources to Achieve Health Equity

Award Number: T35 AI089693
Sponsor: NIH/NIAID
PI: Murphy, Timothy
Award Dates: 09/01/11-08/31/27
Project Title: Training the Next Generation of Clinician Scientists

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2020-present	Co-lead COVID-19 Vaccine Equity Task Force of the Western NY COVID-19 Vaccination Hub
2019-present	Director, UB Community Health Equity Research Institute
2015-present	Director, UB Clinical and Translational Science Institute
2011-present	Director, UB Clinical and Translational Research Center
2011-present	SUNY Distinguished Professor, State University of New York
2009-present	Senior Associate Dean for Clinical and Translational Research, University at Buffalo
2004-present	UB Distinguished Professor of Medicine, University at Buffalo
1995-1996	Visiting Professor, University of Canberra, Australia
1993-2009	Director, Division of Infectious Diseases, University at Buffalo
1992-present	Professor of Medicine and Microbiology, University at Buffalo
1990-2009	Chief, Infectious Diseases, Buffalo VA Medical Center, Buffalo, NY
1988-1990	Chief, Infectious Diseases, Erie County Medical Center
1987-1992	Associate Professor of Medicine and Microbiology, University at Buffalo
1981-1990	Internist, Erie County Medical Center, Buffalo, NY
1981-1987	Assistant Professor of Medicine, University at Buffalo, Buffalo, NY

Other Experience and Professional Membership

National Review Groups

2008-2011	Chair, VA Infectious Diseases B Study Section
2007-2011	NIH Study Section-Clinical Research and Field Studies in Infectious Diseases
1999-2003	Department Veterans Affairs, Infectious Diseases Medical Research Advisory Group
1992-1994	Chair, NIH Study Section, Bacteriology and Mycology 2
1990-present	Multiple NIH study sections (ad hoc panels, special emphasis panels, etc)
1989-2004	Thrasher Research Fund
1989-1994	NIH Study Section, Bacteriology and Mycology 2
1987-2011	VA Merit Review Grants

International Review Panels
The Wellcome Trust (United Kingdom)
Medical Research Council of Canada
National Health and Medical Research Council (Australia)
Medical Research Council (United Kingdom)
Federal Ministry for Research (Germany)
US-Japan Cooperative Medical Sciences Program (Japan)
Netherlands Organization for Health Research and Development

Selected Awards and Honors

2020	Office of Inclusion and Cultural Enhancement's 2020 Community Award of Excellence for Promoting Inclusion and Cultural Diversity, Jacobs School of Medicine and Biomedical Sciences
2015	Outstanding Mentor Award, UB Department of Medicine
2013	Outstanding Research Award, UB Department of Medicine
2011	SUNY Distinguished Professor
2010	Fellow, American Academy of Microbiology
2010	Dean's Award, UB School of Medicine and Biomedical Sciences
2009	Visionary Innovator Award, University at Buffalo
2005	Top 5% of reviewers Journal of Infectious Diseases
2004	University at Buffalo Distinguished Professor
2002	Outstanding Inventor Award (vaccines), State University of New York
2000	Stockton Kimball Award, UB School of Medicine and Biomedical Sciences
1998	Niagara Frontier Inventor of the Year (vaccine development)
1995	Senior International Fellowship, NIH Fogarty Institute
1995	American Society for Clinical Investigation
1994	American Federation for Clinical Research, Eastern Young Investigator Award
1992	Niagara Frontier Inventor of the Year (vaccine development)
1990	Fellow, Infectious Diseases Society of America
1989	Fellow, American College of Physicians

C. Contributions to Science

1. **Bacterial Infection in Chronic Obstructive Pulmonary Disease (COPD):** In an effort to bring clarity and rigor to understanding the role of bacterial infection in the course and pathogenesis of COPD, my colleagues and I conducted a 20-year prospective observational study of bacterial infection in COPD at the Buffalo VA Medical Center, supported by a series Merit Review grants from the Department of Veterans Affairs from 1994 to 2014 of which I was PI from 1994 - 2009. Patients visited monthly and at exacerbations and we collected clinical data, sputum and serum samples. Four selected novel observations from this study

   - A seminal observation is that the acquisition of a new strain of bacterial pathogen triggers most bacterial exacerbations of COPD (a). This paper, cited 1393 times, has resulted in a change in thinking regarding the pathogenesis of bacterial exacerbations, showing that acquisition of new strains drives exacerbations.
   - Adults with COPD are persistently colonized with nontypeable *Haemophilus influenzae* for months to years (b, cited 373 times). The prospective design of the study and analysis of sputum with molecular tools showed that sputum cultures underestimate the role of bacteria in infecting the airways in COPD.
   - *Moraxella catarrhalis* was long ignored as a COPD pathogen. In the first study that relied on prospective data and used careful microbiological techniques, we showed that *M. catarrhalis* is the second most common cause of exacerbations of COPD, causing 2 to 4 million annually in the US (c cited 373).
   - A series of papers from ours and other groups established that chronic colonization in COPD causes airway inflammation and contributes to the course and pathogenesis of COPD (d, cited 1509 times).

   a. Sethi S, Evans N, Grant BJ, **Murphy TF**. New strains of bacteria and exacerbations of chronic obstructive pulmonary disease. N Engl J Med. 2002 Aug 15;347(7):465-71. PMID: 12181400

b. **Murphy TF**, Brauer AL, et al. Persistent colonization by *Haemophilus influenzae* in chronic obstructive pulmonary disease. Am J Respir Crit Care Med. 2004 Aug 1;170(3):266-72. PMID: 15117742

c. **Murphy TF**, Brauer AL, et al. *Moraxella catarrhalis* in chronic obstructive pulmonary disease: burden of disease and immune response. Am J Respir Crit Care Med. 2005 Jul 15;172(2):195-9. PMCID: PMC2718466

d. Sethi S, **Murphy TF**. Infection in the pathogenesis and course of chronic obstructive pulmonary disease. N Engl J Med. 2008 Nov 27;359(22):2355-65. PMID: 19038881

2. **Vaccine Development for Otitis Media and COPD:** Otitis media exacts a huge toll on children and their families. Up to 80% of children have at least one episode of otitis media by the age of 3 years. Up to 20% of children experience recurrent otitis media, which leads to hearing loss and delays in speech and language development. Otitis media is the most common reason for children to receive antibiotics and thus contributes to driving global antibiotic resistance. There is an urgent need for a vaccine to prevent otitis media.

   For the past 30 years I have had a continuous commitment to vaccine development to prevent otitis media in children and infections in adults with COPD. The work has focused on nontypeable *H. influenzae* and *M. catarrhalis*, two of the three most common causes of otitis media. My work identified outer membrane protein P6 of nontypeable *H. influenzae*, a leading candidate vaccine antigen (a). More recently, my laboratory has identified a series of promising vaccine candidates for *M. catarrhalis* (b,c,d). All of my vaccine development work has been supported by the NIH and has resulted in 13 US patents.

   a. **Murphy TF**. Vaccines for Nontypeable *Haemophilus influenzae*: the Future is Now. Clin Vaccine Immunol. 2015 May;22(5):459-66. PMCID: PMC4412935

   b. **Murphy TF**, Kirkham C, et al. Sulfate-binding protein, CysP, is a candidate vaccine antigen of *Moraxella catarrhalis*. Vaccine. 2016 Jul 19;34(33):3855-61. PMID: 27265455

   c. **Murphy TF**, Brauer AL, et al. A Cation-binding Surface Protein as a Vaccine Antigen to Prevent *Moraxella catarrhalis* Otitis Media and Infections in Chronic Obstructive Pulmonary Disease. Clin Vaccine Immunol. 2017 Jun 28. pii: CVI.00130-17. PMCID: PMC5585693

   d. Perez AC, Johnson A, Chen Z, Wilding GE, Malkowski MG, **Murphy TF**. Mapping Protective Regions on a Three-Dimensional Model of the *Moraxella catarrhalis* Vaccine Antigen Oligopeptide Permease A. Infect Immun. 2018 Feb 20;86(3). pii: e00652-17. PMCID: PMC5820933

3. ***Haemophilus influenzae* and *Moraxella catarrhalis* as Pathogens in COPD:** In work supported by two long running R01s, which leverage samples and data from the COPD Study Clinic, my laboratory has contributed several key advances in understanding the pathogenesis and epidemiology of nontypeable *H. influenzae* and *M. catarrhalis* infection. A theme of the work has been the focus on human strains and samples because both of these bacteria are exclusively human pathogens:

   - We sequenced the genomes of 269 strains of *H. influenzae* isolated longitudinally from COPD study. NTHi alters its genome during persistence by regulation of critical virulence functions primarily by slipped-strand mispairing, advancing our understanding adapts to survival in human airways(a).
   - Analysis of sequential isolates of strain that persisted for 543 days in the airways of an adult with COPD revealed that the NTHi genome underwent inversion of a ~400-kb segment three times during persistence. This inversion event resulted in switching of expression two major adhesins (b).
   - A genome mining approach was used to identify a newly recognized virulence factor and vaccine candidate in nontypeable *H. influenzae*. NTHI 1441 mediates invasion of the organism into respiratory epithelial cells, contributing to persistence in human airways (c).
   - *M. catarrhalis* genomes from persistent strains led to the novel observation that the Hag/MID adhesin is important for initial colonization but its expression decreases during persistence in the airways (d).

   a. Pettigrew MM, Ahearn CP, Gent JF, Kong Y, Gallo MC, Munro JB, D'Mello A, Sethi S, Tettelin H, **Murphy TF**. *Haemophilus influenzae* genome evolution during persistence in the human airways in COPD Proc Natl Acad Sci USA. 2018 Apr 3;115(14):E3256-E3265. PMCID: PMC5889651

b. **Murphy TF**, Kirkham C, D'Mello A, Sethi S, Pettigrew MM, Tettelin H. Adaptation of nontypeable *Haemophilus influenzae* in human airways in COPD: Genome rearrangements and modulation of expression of HMW1 and HMW2. mBio 2023 Apr 25;14(2):e0014023. PMID: 36927061 PMCID: PMC10127715

c. Ahearn CP, Kirkham C, Chaves LD, Kong Y, Pettigrew MM, **Murphy TF.** Discovery and contribution of nontypeable *Haemophilus influenzae* NTHI1441 to human respiratory epithelial cell invasion. Infect Immun. 2019 Oct 18;87(11):e00462-19 PMCID: PMC6803334

d. **Murphy TF**, Brauer AL, et al. Persistence of *Moraxella catarrhalis* in COPD and regulation of the Hag/MID adhesin. J Infect Dis. 2019 Apr 16;219(9):1448-1455. PMCID: PMC6467191

4. **Contributions to Premier Medical Textbooks:** Through my clinical activities and research on *Haemophilus influenzae* and *Moraxella catarrhalis*, I have had the opportunity to write 36 chapters, including the most recent editions of the leading textbooks of pediatrics (a), infectious diseases (b, c) and internal medicine (d).

   a. **Murphy TF** (2020) *Moraxella catarrhalis*. In: Kliegman RM, Stanton BF, St. Geme III JW, Schor NF, Behrman RE (eds) Nelson Textbook of Pediatrics 21st Edition. Philadelphia: Elsevier Saunders.

   b. **Murphy TF** (2020) *Haemophilus* species (Including *H. influenzae* and Chancroid). Bennett JE, Dolin R, Blaser MJ (eds) Mandell, Douglas and Bennett's Principles and Practice of Infectious Diseases Ninth Edition.

   c. **Murphy TF** (2020) *Moraxella catarrhalis, Kingella* and other gram negative cocci. Bennett JE, Dolin R Blaser MJ. Elsevier Saunders (eds) Mandell, Douglas and Bennett's Principles and Practice of Infectious Diseases Ninth Edition.

   d. **Murphy TF** (2018) *Haemophilus* and *Moraxella* infections. In: Jameson JL, Kasper DL, Longo DL, Fauci AS, Hauser SL, Loscalzo J (eds) Harrison's Principles of Internal Medicine, 20th Edition. New York: McGraw-Hill Education.

Complete List of Published Work in MyBiblography (233 papers in peer-reviewed journals):
https://www.ncbi.nlm.nih.gov/myncbi/1d7pqQIoOt9k-/bibliography/public/

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BIOGRAPHICAL SKETCH

NAME: Grinslade, Susan M.

eRA COMMONS USER NAME: Susan Grinslade

POSITION TITLE: Clinical Professor, Community Engagement Coordinator, SUNY University at Buffalo School of Nursing & Associate Director of University at Buffalo Community Health Equity Research Institute

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Barnes Hospital School of Nursing, St. Louis, MO	N/A	12/1969	Nursing
Southern Illinois University, Edwardsville, IL	BSN	06/1972	Nursing
Southern Illinois University, Edwardsville, IL	MS Ed	06/1975	Human Services
Southern Illinois University, Edwardsville, IL	MS	06/1990	Nursing
University of Illinois at Chicago, Chicago, IL	PhD	09/2005	Nursing Science

A. Personal Statement

I am qualified to be a co-investigator on this proposal, as a Clinical Professor and Community Engagement Coordinator at the University of Buffalo School of Nursing and a member of the African American Health Equity Task Force and Center, I work closely with the community in addressing and mitigating health inequities through my implementation of community-based health screenings at local African American churches through the provision of health education and promotion, assist in obtaining health insurance and referral to primary care providers.

I have been a Nurse educator with 30 plus years teaching in traditional, accelerated, and RN-BS undergraduate, master, DNP, post-masters, and Ph.D. nursing programs. Areas of teaching include medical-surgical, perioperative, critical care, community, and public health. Areas of research include diabetes self-care management, self-efficacy, social support, and metacognitive strategies to promote critical thinking. I have had a faculty practice with a 13-county Metropolitan Health District (MHD) as a Senior Public Health Nurse responsible for a Tuberculosis Program. As part of my faculty practice with the MHD, I coordinated in-depth health risk assessments for community residents who were potentially exposed to toxic waste through a grant from the Agency for Toxic Substances and Disease Registry (ATSDR). Additionally, I co-lead the implementation of a CDC Demonstration Project to increase the uptake of the influenza vaccine in South Texas. I served in the United States Naval Reserve as a Navy Nurse Corps officer in the Fleet Hospital programs. I was deployed to Desert Storm to serve in a 500-bed Fleet Hospital and oversaw post-anesthesia and critical care wards supervising CRNAs, RN, Navy Corpsman, and Marine Corps E1-E3. I have nursing education administrative experience of ten plus years. I am a public health clinical nurse specialist, and for the last 5 years, I have led an interdisciplinary Million Hearts screening program in collaboration with the Greater Buffalo United Ministry, and currently reactivating this program post-COVID-19.

I am a member of the community-based African American Health Disparity/Equity Task Force, a member of the African American Health Equity Community Center, and an Associate Director of the University at Buffalo Community Health Equity Research Center. I am recently appointed as the Community Engagement Coordinator for the University at Buffalo School of Nursing. I will use my knowledge, expertise, and leadership in using community-based participatory research (CBPR) in coordinating tasks with community partner(s), coordinating the Community Scientific Advisory Board, participating in study implementation and evaluation, and attending regular university and community meetings to discuss project progress.

Ongoing and recently completed projects that I would like to highlight include:

Award Number: COVID-2020C2-11158
Person-Centered Outcomes Research Institute (PCORI)
PI: Chang, Yu-Ping
11/01/20-Present
Comparing Two Ways to Mitigate the Impact of the COVID-19 Pandemic on Mental Health among Adults from Underserved and Racial Minority Communities

Awarded- awaiting award number
Environmental Protection Agency (EPA)
PI: Yoo, Eun-Hye
11/1/22-10/31/25
Improving air quality monitoring for Buffalo African-American Community

Award Number: HS023672001A1
Agency for Healthcare Research and Quality (AHRQ)
PI: Martin, Stan
09/30/19-09/29/20
REACH (Racial and Ethnic Approaches to Community Health)

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2019 – Present	Clinical Professor, Associate Director Community Health Equity Research Institute, Community Engagement Coordinator School of Nursing
2017 – 2019	Clinical Professor, University at Buffalo School of Nursing, Member of the African American Health Equity Task Force.
2009 - 2017	Clinical Professor and Undergraduate Department Chair, University at Buffalo School of Nursing, Buffalo, NY
2006 - 2009	Baccalaureate Program Director, University of Texas Medical Branch School of Nursing, Galveston, TX
2000 - 2006	Assistant Professor, University of Texas Health Science Center at San Antonio, Chronic Nursing Care Department, San Antonio, TX. Public Health Clinical Specialist Metropolitan County Health Department, San Antonio, TX.
1997 - 2001	Research Assistant/Project Director, University of Illinois, College of Nursing, Chicago, IL
1978 - 2000	Instructor, Assistant Director, Associate Professor, Jewish Hospital School/College of Nursing, St. Louis, MO
1972 - 1978	Clinical Nursing Instructor, Lutheran Medical Center, St. Louis, MO

Honors

2023	Selected for Induction as a Fellow American Academy of Nursing, October 2023.
2023	Clinical Scholar Award, SUNY, University at Buffalo, School of Nursing
2019	Distinguished Alumni Award, Goldfarb School of Nursing, Barnes – Jewish College, St. Louis, MO
2016	Teaching Innovation Award, SUNY, University at Buffalo, School of Nursing
2015	Faculty Mentoring Award, SUNY, University at Buffalo, School of Nursing
2002	Army Nurse Corps Scholars Grant Award, UTHSCSA School of Nursing, San Antonio, TX
1998	Edna Malen Scholarship Award, Barnes – Jewish Hospital, St. Louis, MO

C. Contributions to Science

1. My early publications were directly related to my role in clinical practice as a certified diabetes educator (CDE) in a health care center hospital and as a CDE in a Federally Qualified Community Health Center. As a CDE I was challenged by the self-care management issues experienced by patients and providers. This led to my exploration of health behavior theories and their impact on self-care, which ultimately led me to pursue my second master's degree and Ph.D. My earliest publication was driven by a lack of knowledge of

medical-surgical nurses related to caring for patients with ketoacidosis. My role in the preparation of this manuscript was expert clinician related to diabetes management as a CDE.

a. **Grinslade MS**, Buck EA. Diabetic ketoacidosis: Implications for the medical-surgical nurse. Medsurg Nurse. 1999 Feb;8(1):37-45. PMID: 10232211.

2. In addition to the contribution described above, subsequent publications were directly related to my academic work while a doctoral student at the University of Illinois Chicago, where in addition to my role as a student, I was a teaching assistant in the Nursing Measurement Course. In this role, I was responsible for developing and grading assignments to improve students' understanding of psychometrics and measurement issues in research and subsequently serving in a research assistant role with Dr. Kathleen Baldwin. I served as a co-investigator in these studies and co-author, primarily guiding data management and analysis.

a. Baer LC, Baldwin KA, Sisk RJ, Watts P, **Grinslade MS**, Brockschmidt B, Dinger MK, Marion LN, McCubbin J. Development of an instrument to measure community acceptance of nurse practitioners and physician assistants. J Nurs Meas. 1999 Spring;7(1):63-77. PMID: 10394775.

b. Baldwin KA, **Grinslade MS**, Baer LC, Watts P, Dinger MK, McCubbin J. Higher-order factor analysis of an instrument with dichotomous data. Res Nurs Health. 2005 Oct;28(5):431-40. PMID: 16163680.

3. Throughout my doctoral education, I continued to focus on diabetes self-care management challenges for individuals with Type 2 diabetes. Informed by my clinical practice, continuing work as a research assistant, and growing interest in measurement and statistics, my dissertation focused on developing theory-driven research instruments to measure concepts related to self-care management of women with Type 2 diabetes including self-efficacy and social support. Guided by the work of current diabetes expert Russell Glasgow on diabetes self-care management and mentored by Dr. Bandura, I developed a diabetes self-efficacy scale. This product of my dissertation resulted in the publication below.

a. **Grinslade MS**, Paper B, Jing H, Quinn L. Development and psychometric evaluation of the Diabetes Self-Efficacy Scale. J Nurs Meas. 2015;23(1):40-56. PMID: 25985494.

4. The publications below were collaborative research studies and/or projects related to my nursing educator role with undergraduate and graduate nursing students, community health interests, and clinical practice issues related to the Scope of Nursing Practice. My role in the Davilla, et al., (2008) study and publication was as C0-I responsible for facilitating community engagement, study design, methods, data management, and analysis. This study evolved from the increase in HIV-positive diagnoses in a particularly vulnerable female population of Latinx women who were non-English speaking and had limited access to health care services. My role in the Suwanpasu, et al., systematic review and publication was as faculty advisor, clinical practitioner, and co-author. The study and publication by Raines, et al., (2016) evolved from increasing health costs related to increased hospital length of stay secondary to nosocomial infections, inpatient falls, and medico nursing errors, and cost in health care. It was proposed that these costs could be reduced if the bedside nurse was provided additional education in components of health care quality and safety. My role in this study included teaching a course on quality and safety for RN-BS students, co-PI on the study design, data management, analysis, and publication. As technology and clinical interventions have evolved the role and scope of nursing practice have been impacted in multiple practice settings. This has been increasingly evident in the Emergency Room (ER). The practice issue was the basis of the project by Castner, et al., (2013) examining the current protocols in the ER relative to the nursing scope of practice across multiple states in the United States. The outcome of this study was critical to inform changes in the nursing scope of practice and protocols that expanded the RN's role in the ER.

a. Davila YR, Bonilla E, Gonzalez-Ramirez D, **Grinslade MS**, Villarruel AM. Pilot testing HIV and intimate partner violence prevention modules among Spanish-speaking Latinas. J Assoc Nurses AIDS Care. 2008 May-Jun;19(3):219-24. PMID: 18457763.

b. Suwanpasu, S., **Grinslade, S.**, Wu, Yow-Wu, Porock, D. (2014). Risk factors of delirium in elderly patients with hip fracture. *Asian Biomedicine,* 8(2), 157-165.

c. Raines D, **Grinslade MS**, Fabry D, Hewner S, Steeg L. Knowledge and Attitudes of RN-BSN Students Before and After a Patient Safety Course. Nursing Education Perspectives. 37(6), 317-319.

d. Castner J, **Grinslade MS**, Guay J, Hettinger AZ, Seo JY, Boris L. Registered nurse scope of practice and ED complaint-specific protocols. J Emerg Nurs. 2013 Sep;39(5):467-473.e3. PMID: 23639417.

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

NAME: Gomez, Oscar G.

eRA COMMONS USER NAME (credential, e.g., agency login): GOMEZOSCAR

POSITION TITLE: Associate Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Universidad Nacional de Colombia, Bogotá, Colombia	MD	04/1987	Medicine & Surgery
University of Maryland, Baltimore, MD	PhD	03/1994	Microbiology/Immunology
University of Maryland, Baltimore, MD	Postdoc	10/1994	Vaccinology
Max-Plank Institute for Biology, Tuebingen, Germany	Postdoc	11/1997	Bacterial Pathogenesis & Vaccinology
Sinai Hospital of Baltimore, Baltimore, MD	Residency	06/2004	Pediatrics
University of Washington, Seattle, WA	Fellowship	06/2006	Pediatric Infectious Diseases

A. Personal Statement

My biomedical research expertise involves molecular epidemiology of childhood diarrhea affecting children in low resource settings including low- and middle-income countries. My expertise on molecular epidemiology of childhood gastroenteritis includes the identification of *E. coli* pathogens among children with diarrhea in several Latin American countries and the detection of these pathogens among food products for human consumption. These projects were directed to the implementation of cost-effective technologies in countries with limited resources to facilitate epidemiological surveillance of the most common bacterial, viral, and parasitic pathogens associated with childhood diarrhea. My collaborative studies have included investigators from Colombia, Costa Rica, Mexico, Peru, and Uruguay. Despite current knowledge about the etiology of diarrheal disease, there is limited point-of-care diagnostic to screen and diagnosed enteric pathogens in the field. To fill this gap, we designed and developed molecular-based as well as PCR-free technologies to detect diarrheal agents. Successful implementation of these techniques has yielded critical information about the epidemiology of *E. coli* intestinal pathogens among children with diarrhea in different countries and in the US.

I am a member of the Harold Amos Medical Faculty Development program, first as a scholar beginning 2009, and later as an alumnus in 2012. This program is dedicated to the career development of minorities in medical science in the US. I am also a member of the Hispanic Leadership Institute at the State University of New York (SUNY). I am committed to mentorship and career development of individuals underrepresented in health science and clinical practice. I participated as a faculty advisor for the Latino Medical Student Association at Vanderbilt University and now at SUNY Buffalo. I was also a member of the Council on Inclusion in Medicine and Science (CIMS) Executive Committee, University at Buffalo. I am also a Co-Investigator and Associate Program Lead in the University at Buffalo KL2 award, a program to support junior faculty in biomedical science. I provide mentoring and career and professional development to Scholars funded by the grant and members of the Community of Scholars that I chair. I am qualified to serve in the T35 training grant because I have extensive experience as a mentor of underrepresented biomedical science graduate students and postdoctoral trainees and as an active advocate of underrepresented minorities in medical science. As an NIH funded investigator, I have mentored in my laboratory more than 30 undergraduate and graduate students and postdoctoral research and clinical fellows. Furthermore, I am an active member of the diverse workforce in clinical and translational research. Based on the above I am committed to contribute to this grant by leading the research core program that will offer pilot research grants to a new generation of early career scholars to lead observational and

interventional research and propose health policy changes to address and eliminate health disparities. The program will offer an excellence training to scholars in translational science applied to health disparities research.

Ongoing and recently completed projects that I would like to highlight include:

NCATS CTSA KL2
Dubocovich (PI)
08/01/2020-03/01/2025
Clinical and Translational Science Award (KL2): Mentored Career Development Award NCATS

Sklarow Foundation, Buffalo, NY
Gomez (PI)
05/01/11-04/30/23
Lytic bacteriophages as antibiotic alternatives against multidrug resistant bacterial pathogens

NIH/NIAID 5T35AI089693-10
Murphy (PI)
07/2022 – 06/2027
Training the Next Generation of Clinician Scientists

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2020-2022	President of the American Society for Microbiology, Western New York Branch, Buffalo, NY
2016-2016	Associate Professor, Department of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN
2016-present	Associate Professor, Department of Pediatrics, University at Buffalo, The State University of New York, Buffalo, NY
2016-present	Chief Division of Pediatric Infectious Diseases, Department of Pediatrics, University at Buffalo, The State University of New York, Buffalo, NY
2012-present	Visiting Professor, School of Medicine, University of Santander, Colombia
2011-present	Visiting Professor, Department of Biology, Universidad de Cartagena, Colombia
2011-2016	Assistant Professor, Department of Pediatrics, Vanderbilt University School of Medicine, Nashville, TN
2006-2011	Assistant Professor, Department of Pediatrics, University of Iowa College of Medicine, Iowa City, IA
2004-2006	Fellow, Pediatrics Infectious Diseases, University of Washington, Seattle, WA
1998-2001	Instructor, University of Maryland Medical School, Baltimore, MD
1995-1997	Postdoctoral Research Fellow and Director of the Animal Facility, Max Planck Institute for Biology, Tuebingen, Germany
1993-1994	Postdoctoral Research Fellow, Center for Vaccine Development, University of Maryland School of Medicine, Baltimore, MD

Other Experience and Professional Membership

2019	Hispanic Leadership Institute fellowship, SUNY, Albany, NY
2010	Editorial Committee, Revista de Anestesiologia Colombiana
2009-present	Member, Society for Pediatric Research
2004-present	Member, Pediatric Infectious Disease Society
2004-present	Member, Infectious Diseases Society of America
2001-present	Member, American Academy of Pediatrics

Honors

2020-2023	Top Doctors award, Buffalo, NY
2019	Community Service Award of Excellence for Promoting Inclusion and Cultural Diversity. Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, Buffalo, NY
2004	Award for Excellence in Pediatric Basic Research, Sinai Hospital Baltimore, Baltimore, MD

C. Contributions to Science

1. Studies on CS21 pili of enterotoxigenic *E. coli*: My studies of bacterial pathogenesis include the genetic and phenotypic characterization of ETEC pathogens and the role of CS21 (also designated longus) type IV pili of ETEC in gut colonization. ETEC are important causes of diarrhea in travelers and children in the developing world and also re-emerging diarrheal pathogens in the US. Our studies in Colombia indicate that ETEC is the most common *E. coli* pathotype, and the genotypic and phenotypic characterization of the Colombian isolates indicate that they are highly diverse. Despite this extensive diversity, more than 20 of the isolated ETEC strains cluster in well-defined clonal groups that share identical serotype, multiple locus sequence type, enterotoxins, and virulence genes. Virulence factors associated with ETEC diarrheal disease include fimbrial and non-fimbrial colonization factors as well as heat-labile and heat-stable enterotoxins. Our research identified and characterized the gene cluster region encoding the CS21 type IV pili, a highly prevalent ETEC colonization factor. We engineered the first site-directed mutation in the major subunit gene of CS21 and identified the first phenotype specifically associated with CS21, designated microcolony formation, which is characterized by the formation of tiny colonies on agar plates. We found that CS21-mediated microcolony formation protects bacteria against stress factors, suggesting that CS21 provides an advantage to ETEC in the gastrointestinal lumen. In addition, we reported that CS21 mediates adherence to differentiated primary pig intestinal cells and found that adherence is specific. We showed that CS21 is required for ETEC pathogenesis, as survival is significantly greater in mice infected with a CS21 ETEC mutant strain in comparison to those infected with wild-type ETEC. During my doctoral training, we identified a regulatory operon in enteropathogenic *E. coli* (EPEC) designated plasmid-encoded regulators (*per*). We are currently working on the regulation of ETEC CS21 gene expression in collaboration with Dr. Juan Xicotechatl at the Children's University Hospital in Mexico City. The *lngS* and *lngR* regulatory genes located upstream of the major subunit *lngA* are hypothesized to control the expression of CS21.

    a. *Clavijo AP*, Bai J, **Gómez-Duarte, OG**. The Longus Type IV Pilus of Enterotoxigenic *Escherichia coli* (ETEC) Mediates Bacterial Self-aggregation and Protection from Antimicrobial Agents. Microbial Pathogenesis. 2010 Jun;48(6):230-238. PMCID: PMC2860038

    b. Guevara C, Luis WB, Sierra A, Cruz C, Qadri F, Kaushik RS, **Gómez-Duarte, OG**. Enterotoxigenic *Escherichia coli* (ETEC) CS21 fimbriae affects both adhesion to human and pig intestinal cells and pathogenicity in a neonatal mouse model. Microbiol. 2013;159:1725-1735.

    c. Guevara C, Zhang C, Gaddy JA, Iqbal J, Guerra J, Greenberg DP, Decker MD, Carbonetti N, Starner TD, McCray PB Jr, Mooi FR, **Gómez-Duarte OG.** Highly differentiated human airway epithelial cells: a model to study host cell-parasite interactions in pertussis. Infect Dis (Lond). 2016;48(3):177-188. doi:10.3109/23744235.2015.1100323

    d. Kuhlmann FM, Martin J, Hazen TH, Vickers TJ, Pashos M, Okhuysen PC, **Gómez-Duarte OG,** Cebelinski E, Boxrud D, Del Canto F, Vidal R, Qadri F, Mitreva M, Rasko DA, Fleckenstein JM. Conservation and global distribution of non-canonical antigens in Enterotoxigenic Escherichia coli. PLoS Negl Trop Dis. 2019;13(11):e0007825. Published 2019 Nov 22. doi:10.1371/journal.pntd.0007825

2. Enteric vaccines: Building on my strong research interest on vaccines, I worked on the development of live-vaccine vectors using attenuated *Salmonella* as a delivery system. I conducted extensive work during my postdoctoral fellowship at the Center for Vaccine Development, University of Maryland and later or at the Max-Planck Institute, Germany. Work in this area resulted in the discovery that attenuated *Salmonella* can induce strong and specific systemic and mucosal immune responses against delivered bacterial and parasitic antigens and to protect animal models against disease by wild type bacterial challenge. The most remarkable attenuated *Salmonella* vaccines constructs included the *H. pylori* urease-expressing attenuated *Salmonella* Typhymurium vaccine capable to induce strong and specific systemic and mucosal immune responses against urease and, more importantly, capable to protect mice against gastric colonization by *H. pylori*. Also, I was able to express the fragment C of tetanus toxin in attenuated *Salmonella* which upon delivery to a mouse model resulted in strong and specific anti-tetanus toxin antibodies. The vaccine also protected mice against tetanus toxin lethal challenge. Most recently, we reported the first studies on immunogenicity of CS21, a type IV pilus of enterotoxigenic *E. coli* (ETEC). CS21 is essential for ETEC colonization and pathogenesis and it protects ETEC against environmental stress factors within the mammalian host. We evaluated CS21 purified protein in a mouse model and demonstrated that CS21 and LngA major subunit are immunogenic and that they induce strong humoral and mucosal immune responses. More importantly, we

also showed that mice immunized with CS21 plus cholera toxin adjuvant intranasally were able to protect mice from ETEC gut colonization.

a. **Gomez-Duarte OG**, Lucas B, Yan Z, Panthel K, Haas R, Meyer, TF. Urease subunits A and B delivered by attenuated *Salmonella typhimurium* vaccine strain protects mice against gastric colonization by *Helicobacter pylori*. Vaccine. 1998;16:460-471.

b. Chinchilla M, Pasetti MF, Medina-Moreno S, Wang JW, **Gómez-Duarte OG**, Stout R, Levine MM, Galen, JE. Enhanced immunity to *Plasmodium falciparum* circumsporozoite protein using *Salmonella* Typhi expressing PfCSP-encoding DNA vaccine in a heterologous prime-boost strategy. Infect. Immun. 2007 Aug;75(8):3769-3779. PMCID: PMC1951980.

c. Zhang C., J. Iqbal, **O. G. Gomez-Duarte.** 2017. Murine immunization with CS21 pili or LngA major subunit of enterotoxigenic *Escherichia coli* (ETEC) elicits systemic and mucosal immune responses and inhibits ETEC gut colonization. Vet. Microbiol. 202: 90-100.

d. 60. Zhou S, Yu KOA, Mabrouk MT, Jahagirdar D, Huang WC, Guerra JA, He X, Ortega J, Poole ST, Hall ER, **Gomez-Duarte OG**, Maciel M Jr, Lovell JF. 2023. Antibody Induction in Mice by Liposome-Displayed Recombinant Enterotoxigenic *Escherichia coli* (ETEC) Colonization Antigens. Biomed J. 14:S2319-4170(23)00025-2. doi: 10.1016/j.bj.2023.03.001.

3. Molecular Epidemiology of *E. coli* childhood diarrhea: Childhood diarrhea remains an important cause of morbidity and mortality in children under 5 years of age, predominantely in low- and middle-income countries in Africa, Southeast Asia, and some regions in Latin America. My studies in molecular epidemiology of gastroenteritis included the identification of *E. coli* pathogens among children with diarrhea in several Latin American countries, Pakistan and also in the US. I have also conducted field studies on the detection of these pathogens among food products for human consumption. These projects employ cost-effective technologies in countries with limited resources to facilitate epidemiological surveillance of the most common bacterial, viral, and parasitic pathogens associated with childhood diarrhea. Despite current knowledge about the etiology of diarrheal disease, there is no available rapid diagnostic method to identify bacterial pathogens. To fill this gap, we designed and developed molecular-based as well as PCR-free technologies to detect diarrheal agents. Successful implementation of these techniques has yielded critical information about the epidemiology of *E. coli* intestinal pathogens among children with diarrhea in different countries. We were the first to conduct a case-control study to determine the etiology of gastrointestinal infections in children under 5 year of age in Colombia. This study not only identified that viruses are the most important cause of childhood diarrhea but it also identified novel emergent pathogens.

a. Imdad, A F., Foster, M. A F., Iqbal, J P., Fonnesbeck, C., Payne, D. C., Zhang C P., Chappell, J.D., Halasa, N., and **Gómez-Duarte O.G.** 2018. Diarrheagenic Escherichia coli and acute gastroenteritis in children in Davidson County, Tennessee, United States: A case-control study. Ped. Infect. Dis. J. Jun 37(6):543-548. doi: 10.1097/INF.0000000000001908. Corresponding author.

b. Guerra J. A., Zhang C., Bard J. E., Yergeau D.,Halasa N., **OG Gomez-Duarte**. 2020. Comparative Genomic Analysis of a Shiga toxin-producing Escherichia coli (STEC) O145:H25 Associated with a Severe Pediatric Case of Hemolytic Uremic Syndrome in Davidson County, Tennessee, US. BMC Genomics. In press. Corresponding author.

c. Farfán-García A.E., Imdad A F., Zhang C P., Arias-Guerrero M. Y G., Sánchez-Álvarez N. T G., Iqbal J P., Hernández-Gamboa A. E., Slaughter J. C., C. **Gómez-Duarte O.G.** 2020. Etiology of Acute Gastroenteritis among Children less than 5 Years of Age in Bucaramanga, Colombia: a Case-Control Study. PLOS Neg. Trop. Dis. 14(6):e0008375.

d. 56. Iqbal J., Malviya N., Gaddy J., Zhang C., Seier A., Haley K., Doster R., Farfan-Garcia A. E. and **Gómez-Duarte O. G**. C. 2022. Enteroinvasive Escherichia coli O96:H19 is an emergent biofilm-forming pathogen. J. Bact. Mar 28:e0056221. doi: 10.1128/jb.00562-21.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1TyGvgmmcFQ5k/bibliography/public/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

NAME: Noyes, Ekaterina I.

eRA COMMONS USER NAME: Knoyes17

POSITION TITLE: Professor and Division Director

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Saratov State University, Saratov, Russia/ Middlebury College, Middlebury, VT	BS	06/1995	Medical Optics
University of Rochester, Rochester, NY	MS	06/1997	Biophysics
University of Rochester, Rochester, NY	PhD	10/2000	Biophysics/Neurophysiology
University of Rochester, Rochester, NY	MPH	06/2002	Clinical Investigation/Health Services Research

A. Personal Statement

I am Professor and Director of the Division of Health Services Policy and Practice, Department of Epidemiology and Environmental Health, in the School of Public Health and Health Professions, University at Buffalo (UB). I am also Director of Surgical Outcomes and Research (UB SOAR) Center for UB Department of Surgery where I direct a research training program in surgical outcomes. I have a broad background in health services research with expertise in health outcomes, large administrative data analytics, and economic evaluations, as well as mixed methods, team science and implementation research in healthcare. I have specialized in multidisciplinary intervention development and evaluation and have successfully led and participated in numerous interdisciplinary project teams on a variety of projects related to disparities in care access and outcomes. My research program is supported by federal and private sources including NIH, AHRQ, PCORI, and private foundations, among others, focused on reducing disparities in cancer care. I also serve as a mentor on several UB training grants aimed to provide mentored research opportunities to pre- and post-doctoral trainees and junior faculty committed to building research careers in translational and outcomes research.

Through my research, committee and administrative work, I have developed close-working relationships with the co-investigators on the project research team and community stakeholders, which will ensure team efficiency and productivity on this project. Specifically, we have built close collaborations with both rural and urban communities that experience limited access to healthcare services, such as cancer screening and treatment and obstetrics care. Our community partners have been instrumental in helping us design impactful and sustainable interventions and ensure success of implementation process to bring these solutions into a board community setting.

In my role as one of the faculty on the Investigator Development Core, I will be involved in all phases of the core development, from hiring project staff, curriculum development, to data collection and analysis, and will work closely with other team members on the program development, activities and dissemination. With my experience in community based participatory research, academic development and implementation and dissemination science, care delivery and implementation science, I am well-suited to contribute to the proposed project.

Ongoing and recently completed projects that I would like to highlight include:
NHLBI K12 HL138052
Canty/Singh (MPIs)
9/1/17-8/31/23 NCE
UB Clinical Scholar Program in Implementation Science to Achieve Triple Aims

AHRQ R01 HS028000
Hewner (PI)
2/1/21-1/31/2026
Implementing personalized cross-sector transitional care management to promote care continuity, reduce low value utilization, and reduce the burden of treatment for high-need, high-cost patients

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2017-Present Adjunct Professor of Oncology, Roswell Park Comprehensive Cancer Center, Buffalo, NY
2017-Present Director, Team Science Core, UB Clinical and Translational Science Institute (CTSI), Buffalo, NY
2017-Present Research Associate, VA Western New York Medical Center, Buffalo, NY
2016-Present Professor and Director, Division of Health Services Policy and Practice, Department of Epidemiology and Environmental Health, University at Buffalo (UB), Buffalo, NY
2016-Present Clinical Professor of Surgery and Director of Surgical Outcomes and Research (UB SOAR), Department of Surgery, Jacobs School of Medicine and Biomedical Sciences (JSMBS), UB
2016-Present Adjunct Professor, Department of Surgery, University of Rochester Medical School (URMC), Rochester, NY
2015-2016 Director of Regional Engagement and Outcomes, the Judy DiMarzo Cancer Survivorship Program, Wilmot Cancer Institute, Rochester, NY
2015-2016 Expert Team Lead, Multidisciplinary Team Science, Community and Collaborations Domain, University of Rochester's Clinical and Translational Science Institute, Rochester, NY
2013-2016 Professor, Department of Surgery, Scientific Director, Surgical Health Outcomes and Research Enterprise (SHORE), University of Rochester Medical Center, Rochester, NY
2012-2016 Professor, Department of Community and Preventive Medicine/Public Health Sciences, URMC
2008-2012 Division Chief, Health Services Research, Dept. of Community & Preventive Medicine, URMC
2007-2012 Associate Professor, Department of Community and Preventive Medicine, URMC
2002-2007 Assistant Professor, Department of Community and Preventive Medicine, URMC
2000-2002 Research Fellow, Department of Community and Preventive Medicine, URMC

Other Experience and Professional Membership

2021 Grant Reviewer, Career Development (K01, K23, K99) Awards, National Institute on Minority Health and Health Disparities
2021-Present Associate Editor, Implementation Science Specialty Section, Frontiers in Health Services Journal
2020-Present Grant Reviewer, CTSI, Community Engagement/Partnership Development Seed Grant Program, UB
2020 Grant Reviewer, Dissemination and Implementation Research in Health (DIRH) Study Section, Center for Scientific Review, National Institutes of Health
2019-Present Steering Committee, New York State Cancer Consortium
2018-Present External Advisory Board Member, National Institute of Health Research Collaborations for Leadership in Applied Health Research and Care Programme, United Kingdom
2016-Present Member, American Society of Clinical Oncology
2013-Present Member, Surgical Outcomes Club
2000-Present Member, AcademyHealth (2017-2018: Senior Theme Leader/Quality & Value Interest Group)

Honors

2021 Outstanding Senior Researcher of the Year, School of Public Health and Health Professions, UB
2018 Induction into Delta Omega Public Health Honorary Society, Gamma Lambda Chapter, UB
2011 Best Poster Award, International Society of Pharmacoeconomics and Outcomes Research 14th Annual European Congress, Madrid, Spain
2011 AAMC Mid-Career Women Faculty Professional Development Scholar, Austin, TX
2007 Dean's Teaching Fellowship, University of Rochester School of Medicine and Dentistry
2005 Best Short Course Presentation, Society for Medical Decision Making 27th Annual Meet, San Fran, CA

C. Contributions to Science

1. Patient-, Provider- and System-level Drivers of Outcomes in Oncology: The primary goals of this program of research funded by the NIH, Wilmot Cancer Institute, Zeller Corporation, American Society for Colon and Rectal Surgeons (ASCRS) and PCORI are (i) to develop a better understanding of multiple factors affecting cancer outcomes including patient socio-economic characteristics, provider teamwork and regional environment, and (ii) develop and test innovative interventions to minimize the effect of these risk factors. Our findings about the importance of teamwork culture, caregiver engagement and regional care coordination are instrumental in developing new approaches aimed to improve quality of cancer patient care and patient experience through increased use of multidisciplinary care. As a part of this line of work, we created a regional multidisciplinary network of various stakeholders invested in cancer care delivery including patients and their caregivers, public health and health insurance company administrators, oncology and primary care providers, among others. This work provided a foundation for several other studies addressing gaps in cancer care delivery and examining new strategies to close these gaps.

   a. **Noyes K,** Monson JRT, Savastano A, Rizvi I, Green J, Sevdalis N. Regional Multiteam Systems in Cancer Care Delivery. J Oncol Pract. 2016, Nov; 12(11):1059-1066. PMCID: PMC5455419

   b. Shaver AL, Cao Y, **Noyes K**. General Health Care Utilization Among Nonelderly Cancer Survivors Before and After Affordable Care Act Implementation: Early Results. JCO Oncol Pract. 2020 Jul;16(7):e581-e589. PMCID: PMC7359775

   c. Soukup T, Morbi A, Lamb BW, Gandamihardja TAK, Hogben K, **Noyes K,** Skolarus TA, Darzi A, Sevdalis N, Green JSA. A measure of case complexity for streamlining workflow in multidisciplinary tumor boards: Mixed methods development and early validation of the MeDiC tool. Cancer Medicine. 2020 Jul;9(14):5143-5154. PMCID: PMC7367630

   d. Somayaji D, Seo YS, Wilding G, **Noyes K**. A Multilevel Approach to Investigate Relationships Between Health Care Resources and Lung Cancer. Nurs Res. 2022 May 5. PMID: 35510544

2. Implementation of Multidisciplinary Healthcare Programs: The goal of this program of study funded by the NIH, AHRQ, PCORI, Roche Diagnostics International and other sources is to improve efficiency of implementation process for guideline-recommended multidisciplinary interventions in community settings and minimize disparities in health outcomes and economic burden associated with utilization of these interventions and programs. Using the principles of equity-focused implementation and designing for dissemination, we plan to further use these findings to identify the most relevant implementation strategies and examine their comparative effectiveness in reducing health disparities.

   a. Baack-Kukreja JE, Kiernan M, Schempp B, Siebert A, Hontar A, Dolan J, **Noyes K**, Dozier A, Ghazi A, Rashid HH, Wu G, Messing EM. Quality Improvement in Cystectomy Care with Enhanced Recovery (QUICCER Study). BJU Int. 2017;119(1):38-49. PMID: 27128851

   b. Lillvis DF, Willison C, **Noyes K.** Normalizing inconvenience to promote childhood vaccination: a qualitative implementation evaluation of a novel Michigan program. BMC Health Serv Res. 2020 Jul 23;20(1):683. PMCID: PMC7379806

   c. Crabtree-Ide C, Lillvis DF, Nie J, Fagnano M, Tajon RS, Tremblay P, Halterman JS, **Noyes K**. Evaluating the Financial Sustainability of the School-Based Telemedicine Asthma Management Program. Popul Health Manag. 2021 Dec;24(6):664-674. PMID: 33989067

   d. Crabtree-Ide C, Sevdalis N, Bellohusen P, Constine L, Fleming F, Holub D, Rizvi I, Rodriguez J, Shayne M, Termer N, Tomaszewski K, **Noyes K**. Strategies for improving access to cancer services in rural communities: a preimplementation study. Front Health Serv. Epub 28 Jan 2022. doi: 10.3389/frhs.2022.818519. PMCID: PMC Journal in Process.

3. Quality of Care and Value in Health Services Delivery: Guided by the Institute for Healthcare Improvement's Triple Aim and Donabedian's Framework for quality of care assessment, we used multiple sources of administrative, clinical and patient-reported data to explore the complex relationship between regional variation in clinical practices, provider experience and financial incentives, and patient selection. This line of work has been funded by the New York State Empire Clinical Research Investigator Program (ECRIP), Kaleida Health System and the NIH. Using innovative statistical techniques and non-linear methods, we seek

to discover the mechanism behind quality and safety outliers in order to propose more efficient strategies for data collection, quality monitoring, and provide reimbursement.

a. **Noyes K**, Myneni AA, Schwaitzberg SD, Hoffman AB. Quality of MBSAQIP data: bad luck, or lack of QA plan?. Surg Endosc. 2019 Jun 12. PMID: 31190225

b. Kayler LK, Nie J, **Noyes K**. Hardest-to-place kidney transplant outcomes in the United States. Am J Transplant. 2021 Nov;21(11):3663-3672. Epub 2021 Jul 20. PMID: 34212471

c. Hoffman AB, Myneni AA, Towle-Miller LM, Karim SA, Train AT, Burstein M, Schwaitzberg SD, **Noyes K.** The Early (2009–2017) Experience with Robot-Assisted Cholecystectomy in New York State. Annals of Surgery. 2021 Sep 1;274(3):e245-e252. PMID: 34397456

d. Simmonds I, Towle-Miller LM, Myneni AA, Gray J, Jordan JM, Schwaitzberg SD, Hoffman AB, **Noyes K**. Is New York State good at managing hollow viscus injury? Surg Endosc**.** 2022 Jan 7. Online ahead of print. PMID: 34997346

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/katia.noyes.1/bibliography/public/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

NAME: Orom, Heather

eRA COMMONS USER NAME (credential, e.g., agency login): ay6457

POSITION TITLE: Associate Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Marlboro College, Marlboro, VT	BA	05/1997	Comparative Literature
University of Illinois at Chicago, Chicago, IL	MA	05/2003	Social/Personality Psychology
University of Illinois at Chicago, Chicago, IL	PHD	12/2005	Social/Personality Psychology
Wayne State University / Karmanos Cancer Institute, Detroit, MI	NIH training grant	09/2008	Communication and Behavioral Oncology

A. Personal Statement

As a Co-Investigator I will serve on the Steering Committee of the proposed NIMHD Center of Excellence in Investigator Development and Community Engagement. In this role, I will contribute to guiding the strategic priorities of the Center of Excellence and work with the Investigator Development Core to identify mentors for early career investigators on pilot studies and subsequent projects. I will also facilitate partnerships in the School of Public Health and Health Professions to support the goals of the Institute and contribute to selected initiatives of the Center, for example, conferences and workshops. Much of my research, teaching and service is focused on understanding the causes and means of eliminating health inequities. I am experienced in providing training to researchers who want to engage with community partners and conduct health equity research. For years I have taught PhD students best practices for engaging with, and recruiting participants of color and other groups underrepresented in research. I have taught a graduate-level course on health equity for over a decade and provide workshops and seminars for post-doctoral trainees on health equity.

Ongoing and recently completed projects that I would like to highlight include:

R01 CA0197351-02
Hay / Orom (MPIs)
8/13/2015 - 7/31/2020
Don’t Know Responses to Risk Perception Questions: Identifying Mechanisms and Solutions

NSF 2200173
Surtees (PI)
9/012022-02/29/2024
PIPP Phase I: Center for Ecosystems Data Integration and Pandemic

R13TR003486
Murphy (PI)
8/2020-07/2023
Igniting Hope: Mobilizing Community Resources to Achieve Health Equity 2020

1. Holmes LC, Orom H, Lehman HK, Lampkin S, Halterman JS, Akiki V, Supernault-Sarker AA, Butler SB, Piechowski D, Sorrentino PM, Chen Z, Wilding GE. A pilot school-based health center intervention to improve asthma chronic care in high-poverty schools. J Asthma. 2022 Mar;59(3):523-535. PubMed Central PMCID: PMC8281495.

2. Hoffman AB, Myneni AA, Orom H, Schwaitzberg SD, Noyes K. Disparity in access to bariatric surgery among African-American men. Surg Endosc. 2020 Jun;34(6):2630-2637. PubMed PMID: 31385077.
3. Orom H, Sharma C, Homish GG, Underwood W 3rd, Homish DL. Racial Discrimination and Stigma Consciousness Are Associated with Higher Blood Pressure and Hypertension in Minority Men. J Racial Ethn Health Disparities. 2016 Oct 31; PubMed Central PMCID: PMC5411333.
4. Orom H. Nativity and Perceived Healthcare Quality. J Immigr Minor Health. 2016 Jun;18(3):636-643. PubMed PMID: 25957045.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2019 -	Associate Dean for Equity, Diversity and Inclusion, School of Public Health and Health Professions, University at Buffalo, Buffalo, NY
2016 -	Assistant Dean for Equity, Diversity and Inclusion, School of Public Health and Health Professions, University at Buffalo, Buffalo, NY
2015 -	Associate Professor, Community Health and Health Behavior, University at Buffalo, Buffalo, NY
2009 -	Adjunct Professor, Department of Urology, Roswell Park Cancer Institute, Buffalo, NY
2008 - 2015	Assistant Professor, Community Health and Health Behavior, University at Buffalo, Buffalo, NY
2008 - 2015	Assistant Professor, Community Health and Health Behavior, University at Buffalo, Buffalo, NY
2005 - 2008	Agency for Healthcare Research and Quality Post Doctoral Research Fellow, Institute of Gerontology, Wayne State University / Karmanos Cancer Institute, Detroit, MI
2005 - 2008	Member, Communication and Behavioral Oncology Research Program, Population Studies, Karmanos Cancer Institute, Detroit, MI
2000 - 2005	Graduate Research Assistant, University of Illinois at Chicago, Chicago, NY

Honors

2021	Dean's Award, University at Buffalo School of Public Health and Health Professions
2017 - 2018	Society of Behavioral Medicine Leadership Fellow, Society of Behavioral Medicine
2016 - 2017	MAC Leadership Fellow, Mid-American Conference
2015	Citation Abstract, Society of Behavioral Medicine
2014	Outstanding Junior Researcher, University at Buffalo School of Public Health and Health Professions
2012	Civic Engagement Research Dissemination Fellowship, University at Buffalo
2012	Dean's Award for Community Service, University at Buffalo School of Public Health and Health Professions
2012	Citation Abstract, Society of Behavioral Medicine
2010	Citation Abstract, Society of Behavioral Medicine
2005	University Fellowship, University of Illinois Chicago
2003	Student Travel Award, American Psychological Society
2000	University Fellowship, University of Illinois Chicago
1997	Magna Cum Laude, Marlboro College

C. Contributions to Science

1. Disparities in Health Care

I have helped to document that people of color have worse survival rates for many cancers and are also less likely to receive guideline cancer treatment (i.e., conforms to current clinical guidelines), compared to Whites. We have found that Black men with prostate cancer are less likely to receive definitive treatment than their White counterparts. We also report that among prostate cancer patients treated with surgery and for whom a pelvic lymph node dissection would be standard care, Black men are less likely to receive a pelvic lymph

node dissection than Whites men. In another study we found that men with lower socioeconomic status have worse quality of life after treatment for prostate cancer. I have also demonstrated that lower satisfaction with care among people of color and immigrants which has been well-documented, especially among Latinx, is in part, due to receiving less patient-centered care. Finally, colleagues and I have demonstrated gender bias in treatment recommendations for vignette patients presenting with symptoms of coronary heart disease when patients have psychological symptoms. Findings can inform practice and policy change.

a. Biddle C, Fallavollita JA, Homish GG, Orom H. Gender bias in clinical decision making emerges when patients with coronary heart disease symptoms also have psychological symptoms. Heart Lung. 2019 Jul - Aug;48(4):331-338. PubMed PMID: 30595342.
b. Orom H, Biddle C, Underwood W 3rd, Homish GG, Olsson CA. Racial or Ethnic and Socioeconomic Disparities in Prostate Cancer Survivors' Prostate-specific Quality of Life. Urology. 2018 Feb;112:132-137. PubMed Central PMCID: PMC5826752.
c. Moses KA, Orom H, Brasel A, Gaddy J, Underwood W 3rd. Racial/ethnic differences in the relative risk of receipt of specific treatment among men with prostate cancer. Urol Oncol. 2016 Sep;34(9):415.e7-415.e12. PubMed Central PMCID: PMC4996674.
d. Hayn MH, Orom H, Shavers VL, Sanda MG, Glasgow M, Mohler JL, Underwood W 3rd. Racial/ethnic differences in receipt of pelvic lymph node dissection among men with localized/regional prostate cancer. Cancer. 2011 Oct 15;117(20):4651-8. PubMed Central PMCID: PMC3505608.

2. Illness risk perceptions and health disparities

According to nearly all theories of health behavior, perceived risk or beliefs and feelings about being susceptible to getting an illness are a central motivator of protective behavior. I have developed a line of research on the role of perceived risk in cancer inequities. I have found that uncertainty about cancer risk is higher among those with lower education and health literacy, and may be higher among Black people than White people. As we have associated uncertainty about risk with lower engagement in preventive behavior, it is a potential source of health disparities. People who are uncertain about their risk have also been overlooked in the development of health risk communication interventions. We are currently trying to address this gap. In addition, my work in this area is helping to highlight the importance of uncertainty about risk may be a useful addition to theories of health behavior. In a second set of studies I have also repeatedly found that that people of color have lower perceived risk for developing cancer than White people. I have explored the underpinnings of risk appraisals in a community sample of African Americans who, like their nationally representative counterparts had relatively low perceived cancer risk. The most common spontaneously uttered attributions for low risk were: 1) avoiding stating one’s risk was high because this could increase risk (cognitive causation); or 2) hoping it was low (wishful thinking). Both indicate a role for positive thinking as causal agent, a concept that is not currently integrated into most models of perceived risk and has been little studied in the empirical literature. Results of a recent qualitative exploration of perceived risk beliefs among refugees from Burma are similar. My work on racial/ethnic differences in perceived risk and the determinants of these differences is important because it helps researchers to evaluate whether current theories of health behavior are adequate descriptors of behavior change in diverse populations and provides a basis for expanding our models to render them better guides for behavior intervention in diverse populations. In our most recent work I explored prosocial risk perceptions (e.g., perceptions of risk to others) for Covid-19 and found that people of color perceived the risk of contracting the illness to be greater for others compared than did White people, and believed it is more important to protect others. Both are associated with greater engagement in prevention behaviors such as mask wearing.

a. Orom H, Allard NC, Kiviniemi MT, Hay JL, Waters EA, Schofield E, Thomas SN, Tuman M. Racial/Ethnic Differences in Prosocial Beliefs and Prevention Behavior During the COVID-19 Pandemic. J Racial Ethn Health Disparities. 2022 Oct;9(5):1807-1817. PubMed Central PMCID: PMC8405041.
b. Orom H, O'Quin KE, Reilly S, Kiviniemi MT. Perceived cancer risk and risk attributions among African-American residents of a low-income, predominantly African-American neighborhood. Ethn Health. 2015;20(6):543-56. PubMed PMID: 25145570.

c. Orom H, Kiviniemi MT, Shavers VL, Ross L, Underwood W 3rd. Perceived risk for breast cancer and its relationship to mammography in Blacks, Hispanics, and Whites. J Behav Med. 2013 Oct;36(5):466-76. PubMed Central PMCID: PMC3565065.

d. Orom H, Coté ML, González HM, Underwood W 3rd, Schwartz AG. Family history of cancer: is it an accurate indicator of cancer risk in the immigrant population?. Cancer. 2008 Jan 15;112(2):399-406. PubMed PMID: 18072272.

3. Prostate Cancer Treatment Decision Making

Prostate cancer presents unique challenges to the over 230,000 men diagnosed with the disease every year in the U.S. I demonstrated that the decision to treat their prostate cancer can be difficult for about a third of men and have identified personality factors and beliefs that contribute to greater decision-making difficulty and distress shortly after diagnosis. The field recommends that men be highly involved in deciding how to treat their cancer as there are multiple treatment modalities and no clinical trial evidence supporting one over the other. Side effect profiles differ and most men are affected to some degree. We have found that men who are involved in the decision and knowledgeable are indeed more satisfied with their decision and less conflicted about their decision, but also find that making the decision was more difficulty. It may be that are decisional support is still inadequate to support patient-driven decision making. A major concern in prostate cancer care is discouraging over-treatment. I have shown that men who are more emotionally distressed when they are diagnosed are more likely to choose surgery over active surveillance, even if they have low risk disease. These projects confirm that we are still need to develop better ways of supporting men during prostate cancer treatment decision-making. In some cases, informational support is need, but psychosocial support could also help men make better, and possibly easier decisions.

a. Orom H, Underwood W 3rd, Cheng Z, Homish DL, Scott I. Relationships as Medicine: Quality of the Physician-Patient Relationship Determines Physician Influence on Treatment Recommendation Adherence. Health Serv Res. 2018 Feb;53(1):580-596. PubMed Central PMCID: PMC5785307.

b. Orom H, Underwood W 3rd, Biddle C. Emotional Distress Increases the Likelihood of Undergoing Surgery among Men with Localized Prostate Cancer. J Urol. 2017 Feb;197(2):350-355. PubMed Central PMCID: PMC5241229. S

c. Orom H, Underwood W 3rd, Homish DL, Kiviniemi MT, Homish GG, Nelson CJ, Schiffman Z. Prostate cancer survivors' beliefs about screening and treatment decision-making experiences in an era of controversy. Psychooncology. 2015 Sep;24(9):1073-9. PubMed Central PMCID: PMC5514549.

d. Orom H, Homish DL, Homish GG, Underwood W 3rd. Quality of physician-patient relationships is associated with the influence of physician treatment recommendations among patients with prostate cancer who chose active surveillance. Urol Oncol. 2014 May;32(4):396-402. PubMed Central PMCID: PMC4004652.

4. Well-being Across the Prostate Cancer Survivorship Continuum

I have identified determinants of higher distress among men diagnosed with prostate cancer. As a second set of findings also indicate that early distress predicts distress later in survivorship, early intervention for those who a highly distress may be warranted. Identifying factos associated with distress will contribute to designing these interventions. We have also found that men with stronger spiritual beliefs find it easier to make the treatment decision and have less regret about their decision six months after treatment, compared to men with less strong spiritual beliefs. We have found that there are some racial-ethnic and socioeconomic disparities in quality of life after treatment, although African American men may have advantages in some domains. Results suggest that, especially low income men, could be better supported with post-treatment care, including interventions for erectile dysfunction. Finally, we have found that emotional distress and physical quality of life after treatment are reciprocally related. This work is important because it further underlines the potential roles of psycho-social care, adequate treatment of side effects, and possibly, the role spiritual care in improving prostate cancer survivorship.

a. Orom H, Biddle C, Underwood W 3rd, Nelson CJ. Worse Urinary, Sexual and Bowel Function Cause Emotional Distress and Vice Versa in Men Treated for Prostate Cancer. J Urol. 2018 Jun;199(6):1464-1469. PubMed Central PMCID: PMC7197257.

b. Orom H, Biddle C, Underwood W 3rd, Homish GG, Olsson CA. Racial or Ethnic and Socioeconomic Disparities in Prostate Cancer Survivors' Prostate-specific Quality of Life. Urology. 2018 Feb;112:132-137. PubMed Central PMCID: PMC5826752.

c. Orom H, Biddle C, Underwood W 3rd, Nelson CJ, Homish DL. What Is a "Good" Treatment Decision? Decisional Control, Knowledge, Treatment Decision Making, and Quality of Life in Men with Clinically Localized Prostate Cancer. Med Decis Making. 2016 Aug;36(6):714-25. PubMed Central PMCID: PMC4930707.

d. Orom H, Nelson CJ, Underwood W 3rd, Homish DL, Kapoor DA. Factors associated with emotional distress in newly diagnosed prostate cancer patients. Psychooncology. 2015 Nov;24(11):1416-22. PubMed Central PMCID: PMC5549449.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/heather.orom.1/bibliography/public/

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BIOGRAPHICAL SKETCH

NAME: Pointer, Kinzer M.

eRA COMMONS USER NAME: KINZERPO

POSITION TITLE: Pastor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Canisius College, Buffalo, NY	BA	05/1985	History Education and Political Science
Rochester Center for Theological and Biblical Studies	BCM	11/2019	Christian Ministry
	MTh	05/2021	Master of Theology
	DMin(ABD)	05/2024	Doctor of Ministry

A. Personal Statement

I am the Pastor of Agape Fellowship Baptist Church, Liberty Missionary Baptist Church, Chairman of the Board Managers of Millennium Collaborative Care, Chairman of the Erie County Poverty Commission, Board Chair of the Greater Buffalo United Ministries and Board Secretary of Child Care Resource Network, Board Member of the Erie County Medical Center Corporation, President and CEO of African Heritage Food Co-Op.

I am the convener of the Concerned Clergy Coalition of Western New York. I am a co-convener of the African American Health Equity Task Force and the Buffalo Center of Health Equity. I am a Board member of the University at Buffalo Community Health Equity Research Institute, as well as a member of the Community Advisory Board of the SUNY at Buffalo CTSI. I have spent the last 10 years working in multiple ways to eradicate the social determinants of health in the Black and Brown communities of the Greater Buffalo region. I have joined the Board of Trustees for Erie County Medical Center. I am the President and CEO of the African Heritage Food Co-Op. I am committed to continuing these works towards completion!

In this proposed Center of Excellence, I am thrilled to work with Dr. Timothy Murphy and others to ensure that we begin earnestly to prepare a new generation of Scientific Investigators who will focus on our ability to improve health outcomes and work to the goal of eradicating health disparities, especially those impacted by the social determinants of health driven by race-based policies and practices. In my role here, I will collaborate with my colleagues and the community, we will recruit and train, with the assistance of the community and scientific investigators who will become competent in working in and alongside the Community.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2023 Present President and CEO, African Heritage Food Co-Op
2019-Present Pastor, Liberty Missionary Baptist Church
2019-Present Board Member, SUNY @ Buffalo Community Health Equity Research Institute
2017-Present Adjunct Faculty, Jacobs School of Medicine and Biomedical Sciences
2014-Present President and CEO, Greater Buffalo United Ministries, LLC (founder)
2010-Present Pastor, Agape Fellowship Baptist Church
2007-2013 Coordinator of Parent and Community Services, Enterprise Charter School of Buffalo
2004-2011 Coordinator, Enterprise Charter School
2000-2008 President, District Parent Coordinating Council of the Buffalo Public Schools
1989-1995 Protestant Chaplain, Erie County Correctional Facility

Other Experience and Professional Membership

2014-Present	Concerned Clergy Coalition of Western New York (founding member)
2007-2011	Member, Board of Education, City of Buffalo Public School District
2004-2007	Board of Trustees, Western New York Maritime Charter School
2002-2013	Board Member, Project Flight, Inc

C. Contributions to Science

N/A

Complete List of Published Work in MyBibliography: N/A

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

NAME: Silverman, Robert Mark

eRA COMMONS USER NAME: SILVERMAN35

POSITION TITLE: Professor of Urban and Regional Planning

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Arizona State University, Tempe, AZ	BS	05/1989	Political Science
Arizona State University, Tempe, AZ	MPA	12/1991	Public Administration
University of Wisconsin, Milwaukee, WI	PHD	05/2007	Urban Studies

A. Personal Statement

I am a Professor of Urban Planning. My research focuses on affordable housing, neighborhood planning, and community development policies. I have broad background in urban studies topics with an emphasis on social equity and citizen participation in the planning process. My research applies mixed methods, and I have expertise in qualitative and community-based policy research. I am the co-author of one of the only textbooks with a specific focus on qualitative research methods for community development. An undergirding theme of that textbook is the incorporation of participatory research techniques across qualitative research design. I have built foundational skills for the proposed project as a PI and co-investigator on several extramural grants that have incorporated community-based research methods. Past projects I have worked on will inform the proposed project. They include: “Turning the Corner” (co-investigator) funded by the Ralph Wilson, Jr. Foundation; “Analysis of Impediments for Fair Housing Choice” (co-investigator) funded by the Erie County Urban County Consortium; “University at Buffalo Neighborhood Transformation Community Outreach Partnership Center (UBNT-COPC),” (co-investigator) funded by United Stated Department of Housing and Urban Development (HUD); and the “Housing Service Agency Structural Definition Report,” (PI) funded by the Buffalo Branch of the Federal Reserve Bank of New York. Each of these projects involved collaborative research with community stakeholders and other methods. In summary, I have the training, expertise, and experience working with research teams, and the motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

Baldy Center Small Grant, The Baldy Center for Law and Social Policy, University at Buffalo
Silverman (PI)
06/01/21-12/31/22
Some public housing authorities (PHAs) get it right: successful implementation of the U.S. Department of Housing and Urban Development’s (HUD’s) small area fair market rent (SAFMR) rule

Baldy Center Small Grant, The Baldy Center for Law and Social Policy, University at Buffalo
Silverman (PI)
06/01/19-5/31/20
Who lives in the worst government subsidized housing?: A demographic analysis of residential patterns in U.S. Department of Housing and Urban Development (HUD) properties

Research Grant, Poverty Race & Research Action Council (PRRAC)
Patterson (PI)
08/01/18-07/31/19
Small area fair market rents (SAFMRs): Best practices and the scope of institutional and community support for their expansion

Citations:

a. Patterson KL, Santiago AM, **Silverman RM.** The enduring backlash against racial justice in the United States: Mobilizing strategies for institutional change. Journal of Community Practice. 29(4): 334-344.

b. **Silverman RM**, Patterson KL. Qualitative research methods for community development. 2nd Edition. New York: Routledge.

c. **Silverman RM**, Taylor HL Jr, Crawford CG. The role of citizen participation and action research principles in Main Street revitalization: An analysis of a local planning project. Action Research. 6(1): 69-93.

d. **Silverman, R.M.**, Taylor, H.T., Yin, L., Miller, C. and Buggs, P. Are we still going through the *empty ritual of participation*?: Inner-city residents' and other grassroots stakeholders' perceptions of public input and neighborhood revitalization in Buffalo, NY. Critical Sociology, 46(3): 413-428.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2021-Present	Affiliated Faculty, University at Buffalo Center for Cannabis and
2014-Present	Professor, Department of Urban and Regional Planning, University at Buffalo Cannabinoid Research (CeCaR), University at Buffalo
2021-2022	National Science Foundation, Advisory Panel for the Build and Broaden: Enhancing Social, Behavioral and Economic Science Research and Capacity at Minority-Serving Institutions Research Grant Program
2017-2018	Urban Affairs Association, Governing Board Chair
2015-2017	Urban Affairs Association, Governing Board Vice Chair
2019-Present	Editorial Board, Journal of Policy Practice and Research
2018-Present	Editorial Board, Journal of Community Practice
2012-2018	Urban Affairs Association, Governing Board
2005-2013	Editorial Board, Community Development: Journal of the Community Development Society
2005-Present	Editorial Board, Critical Sociology
2003-Present	Senior Research Fellow, Center for Urban Studies, University at Buffalo
2003-2013	Associate Professor, Department of Urban and Regional Planning, University at Buffalo
2003	Associate Professor, Department of Sociology, Wayne State University
2000-2003	Assistant Professor, Department of Sociology, Wayne State University
1998-2000	Assistant Professor, Department of Urban and Regional Planning, Jackson State University

Honors

2014	Article of the Year Award, Leadership and Policy in Schools, "Urban, suburban and rural contexts of school districts and neighborhood revitalization strategies: Rediscovering equity in education policy and urban planning."
2012	Emerald Literati Network, Highly Commended Article Award, International Journal of Public Sector Management, "The effects of perceived funding trends on nonprofit advocacy: A national survey of nonprofit advocacy organizations in the United States."
2009	Scott Greer Award for Postgraduate Achievement in the Study of Urban Social Institutions, University of Wisconsin, Milwaukee.
1992	Outstanding Graduate, College of Public Programs, Arizona State University

C. Contributions to Science

1. A substantial portion of my early publications focused on empirically analyzing the public participation process in urban communities. This research was based on qualitative analysis done in Jackson, MS, Detroit, MI, Buffalo, NY and other cities. It focused on participatory processes used by local government, nonprofit organizations, and grassroots advocacy groups. This body of work was used to inform the development of theory on public participation and advocacy.

a. **Silverman RM.** Citizens' district councils in Detroit: The promise and limits of using planning advisory boards to promote citizen participation. National Civic Review. 92(4): 3-13.

b. **Silverman RM.** Progressive reform, gender, and institutional structure: A critical analysis of citizen participation in Detroit's community development corporations (CDCs). Urban Studies. 40(13): 2731-2750.

c. **Silverman RM.** Caught in the middle: Community development corporations (CDCs) and the conflict between grassroots and instrumental forms of citizen participation. Community Development. 36(2): 35-51.

d. **Silverman RM**. Sandwiched between patronage and bureaucracy: The plight of citizen participation in community-based housing organizations (CBHOs). Urban Studies. 46(1): 3-25.

2. A related stream of my work has focused on the relationship between institutions engaged in the urban development process and their impacts on minority communities. In particular, this research has examined the impacts of neighborhood revitalization processes on patterns of residential displacement and efforts to promote equitable development.

   a. Belongie N, **Silverman RM.** Model CBAs and Community Benefits Ordinances as Tools for Negotiating Equitable Development: Three Critical Cases. Journal of Community Practice. 26(3): 308-327.

   b. **Silverman, RM.** CDCs and charitable organizations in the urban South: Mobilizing social capital based on race and religion for neighborhood revitalization. Journal of Contemporary Ethnography. 30(2): 240-268.

   c. **Silverman RM**, Lewis J, Patterson KL. William Worthy's concept of 'institutional rape' revisited: Anchor institutions and residential displacement in Buffalo, NY. Humanity & Society. 38(2): 158-181.

   d. **Silverman RM**, Taylor H, Yin L, Miller C, Buggs P. There Goes Our Family Friendly Neighborhood: Residents' Perceptions of Institutionally Driven Inner-City Revitalization in Buffalo, NY. Journal of Community Practice. 27(2): 168-187.

3. My research has also empirically examined affordable housing policy and patterns of disinvestment in urban neighborhoods. This work has focused on questions of spatial equity in terms of investment in inner city neighborhoods and residential mobility.

   a. Patterson KL, **Silverman RM**, Wang C. It's not always sunny in San Diego for Housing Choice Voucher (HCV) holders: The reproduction of racial and socioeconomic segregation under the Choice Communities Initiative. Journal of Policy Practice and Research. 2(2): 76-89.

   b. **Silverman RM**, Yin L, Patterson KL. Dawn of the dead city: An exploratory analysis of vacant addresses in Buffalo, NY 2008-2010. Journal of Urban Affairs. 35(2):131-152.

   c. **Silverman RM**, Patterson KL, Yin L, Ranahan M, Wu L. Affordable housing in US shrinking cities: From neighborhoods of despair to neighborhoods of opportunity?. Bristol: Policy Press.

   d. Yin L, Yin F, **Silverman RM.** Spatial clustering of property abandonment a in shrinking cities: A case study of targeted demolition in Buffalo, NYs African American neighborhoods. Urban Geography, Online First.

Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/robert.silverman.2/bibliography/public/

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BIOGRAPHICAL SKETCH

NAME: St. Vil, Christopher

eRA COMMONS USER NAME: CSTVIL

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
State College, Buffalo, NY	BSW	2000	Social Work
State University of New York at Stony Brook, Stony Brook, New York	MSW	2002	Social Work
Howard University, Washington, DC	PHD	2012	Social Work
University of Maryland, College Park	Post Doc	2015	African American Studies

A. Personal Statement

My background is in social work with specific training in both quantitative and qualitative methods as well as evaluation. My research broadly focuses on masculinity with an emphasis on black males from marginalized neighborhoods who have experienced violent victimization. My specific research interests include victimization, mentoring, and evaluation design with the ultimate goal of informing interventions that promote the health of black males in the U.S. These experiences have positioned me as a researcher that specializes in data collection procedures with black and brown men. My evaluation research, most pertinent to this application, has led me to have extensive experience interviewing black males and informing interventions that improve their outcomes. For example, I have served as the principal investigator or co-investigator on several studies that attest to this. My focus group work with black men in organizations of faith has led to culturally specific approaches to address domestic violence within black churches in Washington, DC (Bent-Goodley, Henderson, Youmans, & St. Vil, 2015). During my post-doctoral training, I served as the co-investigator of a longitudinal ethnographic study that explored correlates of victimization among black men who experienced violent injury. That research led to a number of publications, one of which that led to suggestions for how researchers could engage black males in research within a hospital setting (St. Vil, Richardson, & Cooper, 2018). Also, I have successfully evaluated a mentoring program through qualitative interviews with black males that have informed a body of work with regard to engaging educationally disconnected young males (St. Vil & Angel, 2018). My research and experience at the intersection of masculinity (male help-seeking) and victimization have informed my expertise in the area of recruiting, retaining and successfully engaging black men and their families in community-based research. These experiences make me well suited to contribute to the development of researchers in conducting community-based research in marginalized Black communities.

Ongoing and recently completed projects that I would like to highlight include:

15POVC-22-GK-01799-NONF
Victim of Crime Act Administrators (VOCA)
St. Vil (PI)
10/1/21-9/30/22
Facilitating Organizational Change at SNUG Buffalo

2017-SMSV-006
Office of Victim Service and Justice Grants (OVSJG)
St. Vil (PI)
10/1/17-9/30/20
Supporting Male Survivors of Violence

3R21MD013486-01S1
National Institute on Minority Health and Health Disparities
Megan Moore (PI)
4/1/19-12/31/2020
Achieving Injury-related Health Equity in the National Trauma Healthcare System

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2015-	Assistant Professor, University at Buffalo (SUNY) School of Social Work
2013-2015	Co-Investigator, University of Maryland, Dept. of AAS
2010-2012	Research Analyst, Westat Research Corporation
2010-2011	Research Assistant, University of Maryland, Dept. of AAS
2006-2008	Research Assistant, Casey Family Programs
2006	Research Assistant, Howard University School of Social Work
2005	Research Assistant, Howard University School of Social Work
2005	Research Assistant, Council of the District of Columbia

Other Experience and Professional Memberships

2016	Social Work
2015-	Institute for Community Health Promotion Fellow (SUNY Buffalo State)
2014-	American Evaluation Association
2010	Culturally Responsive Evaluation Association

C. Contributions to Science

1. Interventions to reduce interpersonal violence. My research focuses broadly on masculinity with an emphasis on marginalized black males. As a result, my publications tend to focus on solutions and interventions to issues that plague black males as a demographic group. One issue that plagues black males is their environmental contexts. As a result of living in dangerous environments, young black males are often exposed to parenting strategies and environmental stimuli that are unique to their experience and increase the likelihood for negative outcomes. The following publications discuss the parenting strategies that some male youth contend with, including being brought to law enforcement as an intervention strategy by their parents or experiencing exile. I have also used ethnographic methods to understand why some delinquent black male youth choose to maintain distal relationships with neighborhood peers. We found that maintaining these relationships is a safety strategy for these youth, known as “rolling dolo,” rather than a friendship characterized by mutual trust, obligation, and reciprocity. Finally, I have participated in efforts to understand the relationship of income inequality and racial segregation with fatal interactions with police.

    a. Richardson JB Jr, Van Brakle M, **St Vil C**. Taking boys out of the hood: exile as a parenting strategy for African American male youth. New Dir Child Adolesc Dev. 2014 Mar;2014(143):11-31. PMID: 24677646.

    b. Richardson JB Jr, Johnson W, **St Vil C**. I want him locked up: Juvenile confinement as a parenting strategy for pre-delinquent African-American male youth. Journal of Contemporary Ethnography, 43(4), 488-522.

    c. Richardson JB Jr, **St Vil C**. Rolling dolo: Desistance from delinquency and negative peer relationships over the early adolescent life course. Ethnography.

    d. Johnson O Jr, **St Vil C**, Gilbert KL, Goodman M, Johnson CA. How neighborhoods matter in fatal interactions between police and men of color. Soc Sci Med. 2019 Jan;220:226-235. PMID: 30472515.

2. Violent trauma recidivism. My research of victimization focuses on trauma recidivism, which refers to multiple episodes of emergency room or trauma center visits as a result of violent injury. One method to reduce the likelihood of violent victimization is to engage them in the emergency room during the “Golden hour,” when they may be more susceptible to receiving help to avoid a subsequent victimization. This interest has naturally led me to the evaluation of hospital-based violence intervention programs and to a research agenda that seeks to identify mediators and moderators of violent victimization among men of color. While some of

my publications identified above seek to reduce the likelihood of victimization among men of color, they do so within the community context. From this work, I have published on valuable lessons in recruiting and maintaining contact with black male participants in research, including using innovative methods such as social media to follow-up with participants.

a. Richardson JB, **St Vil C**, Sharpe T, Wagner M, Cooper C. Risk factors for recurrent violent injury among black men. J Surg Res. 2016 Jul;204(1):261-6. PMID: 27451895.

b. **St Vil C**, Richardson J, Cooper C. Methodological Considerations for Research With Black Male Victims of Violent Injury in an Urban Trauma Unit. Violence Vict. 2018 Apr 1;33(2):383-396. PMID: 29609682.

c. **St Vil C**, Hall EC, Sheppard M, Williams M. Testing the efficacy of a hospital-based violence intervention programme: protocol and design. Inj Prev. 2020 Dec 16:injuryprev-2020-044026. PMID: 33328172.

d. Njus MM, **St Vil C**, Sheppard M, Hall EC. Hospital-Based Violence Intervention Programs: An Essential Relief System in the COVID-19 Pandemic. J Am Coll Surg. 2021 Nov;233(5):S296. PMCID: PMC8531702.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/14mtOY5bZmlwEy/bibliography/58202764/public/?sort=date&direction=ascending.

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BIOGRAPHICAL SKETCH

NAME: Taylor, Henry, L., Jr.

eRA COMMONS USER NAME: HLTAYLOR

POSITION TITLE: Director (University at Buffalo Center for Urban Studies) and Professor (U.B. Department of Urban and Regional Planning)

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
SUNY Buffalo, Buffalo, NY	Ph.D.	05/1979	Urban History
SUNY Buffalo, Buffalo, NY	M.A.	05/1973	Urban History
University of Tennessee, Knoxville, TN	M.A.	05/1966	Clinical Audiology
Tennessee A&I State University, Nashville, TN	B.S.	05/1965	Speech Pathology and Audiology

A. Personal Statement

I am a historian and urban planner with a health science background. I have a B.A. and M.A. in clinical audiology and directed an audiology clinic for three years. My current research focuses on the relationship between city building and health outcomes in urban neighborhoods, particularly marginalized, underdeveloped neighborhoods of color. My research seeks to understand how the interplay among the urbanization process, structural racism, and the economy produce underdeveloped neighborhoods where substandard housing, under-resourced schools, unkept sidewalks, polluted environments, and other adverse social determinants cause undesirable health outcomes and delimit the life chances of its residents. This research aims to build a bridge between the health sciences and urban planning, which facilitates the development of innovative intervention strategies to improve health outcomes among Blacks and other people of color. To deepen my understanding of the causal relationship between adverse health outcomes and the built environment, I am studying the link between the residential segregation process and health outcomes, the connection between substandard housing and undesirable health outcomes in Buffalo, and the causal link between gun violence and the social determinants of health in New York State.

Over the years, I have been engaged in numerous participatory neighborhood planning projects in Buffalo, New York, and elsewhere. As a member of the Jacobs School of Medicine's Medical Education and Educational Research Institute and Associate Director of the Community Health Equity Research Institute, I developed a course with others on health and the neighborhood to deepen understanding of the relationship between the social determinants of health and adverse health outcomes in the Black community. I am also working with the Jacobs faculty on an anti-racist four-year medical curriculum and have conducted an annual 5-week workshop, sponsored by the Clinical and Translational Science Institute, on competencies in health equity that over 500 health practitioners attended. Additionally, I have worked with young scholars interested in the social determinants of health. The current application builds on my knowledge base and unique experiences. I will play a key role in training the next generation of health equity researchers by helping to deepen their understanding of marginalized, underdeveloped neighborhoods, developing interdisciplinary community participatory research teams, and aiding in outreach and building the community research infrastructure of neighborhoods. I will participate in building a bridge between health equity researchers and communities of color. The following four publications highlight my experience and qualifications for this project.

a. Taylor, H.L., Jr. (2021). Region Central: Residential Segregation, Housing Inequity, and Neighborhood Inequality. A Report to the Stantec Consultant Services. June. 1- 45.

b. Taylor, H.L., Jr. (2021). The Harder We Run: The State of Black Buffalo in 1990 and the Present. A Report to the Buffalo Center for Health Equity. September. 1- 85.
c. Taylor, H.L., Jr. (2020). Disrupting market-based predatory Development: Race, class, and the underdevelopment of Black neighborhoods in the U.S. Journal of Race, Ethnicity and the City. DOI10.1080/26884674.2020.1798204.
d. Luter, Gavin, Taylor, H.L., Jr. (2020). Building the Neighborly Community in the Age of Trump: Toward a University-Community Engagement Movement 3.0 in Robert Kronick (Ed.). Emerging Perspectives on Community Schools and Engaged Universities. IGI Global.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2020-Present	Associate Director, Community Health Equity and Research Institute, University at Buffalo
1996-Present	Professor, Department of Urban and Regional Planning, University at Buffalo
1987-1996	Associate Professor, Department of American Studies, University at Buffalo
1987-Present	Director, Center for Urban Studies
1980-1987	Assistant Professor, Departments of History and Black Studies, The Ohio State University
1976-1979	Director of Learning Resource and Minority Recruitment, the University of Cincinnati Medical School
1974-1976	Director of Employee's Developmental Educational Program, University of Cincinnati,
1968-1970	Instructor, Speech and Audiology, Hampton Institute
1967-1968	Director of Clinical Audiology, Hampton Roads Speech and Hearing Clinic, Newport News, Virginia

Other Experience and Professional Memberships

2022-2023	New York State 400 Years of African American History Commission
2018-2023	President, Board of Directors, King Urban Life Center
2015-2023	Erie County Poverty Committee
2010-2023	Board of Editors, Universities and Community Schools
2000-2023	American Collegiate Schools of Planning
1990-2023	Urban Affairs Association
1990-2023	Urban History Association
1993-2023	American Planning Association

Honors

2022	Community Healer Award. Community Healing Network
2021	The Harder We Run: Report on the Status of Black Buffalo
2018	Marilyn J. Gittell Activist Scholar Award, The Urban Affairs Association
2016	Excellence in University-Community Engagement Award: Sustained Contribution, University at Buffalo
2012	Lee Benson Activist Scholar Award, the Netter Center for Community Partnerships, University of Pennsylvania
2008	Outstanding Program Award-East Side Neighborhood Transformation Partnership, The Community Development Society
2005	Distinguished Leadership, Michael J. Krasner Professional Planner Award, American Planning Association, New York Upstate Chapter, Western New York Section

C. Contributions to Science

1. My contribution to science focuses on understanding the relationship between city building, urbanization, structural racism, and the underdevelopment and marginalization of Black neighborhoods and other communities of color. The work indicates that social determinants of health are primarily rooted in black neighborhood space and result from choices and decisions on how we build cities in the United States. The conditions found in these communities are not due to poverty or natural causes but rather to policymakers' conscious choices and decisions.

a. **Taylor HL**. The Historical Roots of the Crisis in Housing Affordability: The Case of Buffalo, New York 1920-1950. Fair and Affordable Housing in the U.S.: Trends, Outcomes, Future Directions (Vol. 33, pp. 245-276).

b. **Taylor HL.** Disrupting market-based predatory development: Race, class, and the underdevelopment of Black neighborhoods in the U.S. Journal of Race, Ethnicity and the City. 1(1-2), 16-21.

c. **Taylor HL.** Land Values and the Enduring Significance of Racial Residential Segregation. Poverty & Race. 30:1. January-April.

d. Taylor, H.L., Jr. (2021). Land Values and the Enduring Significance of Racial Residential Segregation, in (eds). Haberle, M., K. House, *Racial Justice in Housing Finance: A Series on New Directions.* PRRAC. May.

2. My research has also contributed to our understanding of the challenges of community engagement and getting residents involved in research, neighborhood planning, and community development activities.

   a. Silverman RM, **Taylor HL**, Yin L, Miller C, Buggs P. Are We Still Going Through the Empty Ritual of Participation? Inner-City Residents' and Other Grassroots Stakeholders' Perceptions of Public Input and Neighborhood Revitalization. Critical Sociology. 1-16.

   b. Silverman RM, **Taylor HL**, Yin L, Miller C, Buggs P. There goes our family friendly neighborhood: Residents' perceptions of institutionally driven inner-city revitalization in Buffalo, NY. Journal of Community Practice. 27(2), 168-187.

   c. **Taylor HL**. Participatory Democracy, Neighbourhood Revitalization and the Promise of the University at Buffalo in Sjur Bergan, Ira Harkavy, and Hillgie van't Land. Strasbourg Cedex: Council of Europe Publishing. 157-166.

3. A third scientific contribution has been on the impact of gentrification on Black neighborhood development. The work identifies the role of market dynamics in making it difficult to build stable, mixed-income neighborhoods for Blacks and people of color. The reason is that market dynamics spawn increases in rent and home values that displace and eventually remove most of the low-income residents.

   a. Luter G, **Taylor HL**. Building the Neighborly Community in the Age of Trump: Toward a University-Community Engagement Movement 3.0 in Robert Kronic. IGI Global.

   b. Silverman RM, **Taylor HL,** Yin L, Miller C, Buggs P. Perceptions of Residential Displacement and Grassroots Resistance to Anchor Driven Encroachment in Buffalo, NY. Urbanites. 8:2 (November). 79-86.

   c. **Taylor HL**, Silverman RM, Yin L. Buffalo Turning the Corner. The Wilson Foundation. 1-95.

4. A fourth area of research has studied the built environment's impact on health outcomes in the Black community. The work has demonstrated that a strong correlation exists between neighborhood conditions and health outcomes. Its findings suggest that improvements in health outcomes will be limited unless neighborhoods of color are revitalized for the people living there.

   a. **Taylor HL**. The Pre-COVID-19 World: Race and Inequality in Higher Education in (eds). Bergan, S., Harkavy, I. The Higher Education Response to the COVID-19 Pandemic: Responsibility for a Sustainable Future. The Council of Europe Higher Education Series.

   b. **Taylor HL**. Striving for a Healthier Buffalo: A Community Needs Assessment for the Greater Buffalo United Ministries.

   c. **Taylor HL**, Brody D, Hahn-Baker D. Meeting the 21st Century Housing Challenge: Building a Minimum Housing Standard in Erie County. December 31. Erie County Legislature.

   d. **Taylor HL**. The Health Status of the Near East Side Community and Neighborhood Conditions. Kaleida Health.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/collections/mybibliography/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Van Zile-Tamsen, Carol

eRA COMMONS USER NAME (credential, e.g., agency login): CAROLVAN

POSITION TITLE: Associate Vice Provost and Director

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Pittsburgh at Bradford	BS	04/1989	Psychology
University of Pittsburgh at Bradford	BA	04/1989	English
University at Buffalo	MEd	05/1991	College Counseling
University at Buffalo	PhD	05/1996	Educational Psychology

A. Personal Statement

As the Program Evaluator on the P50 center grant, entitled “Specialized Centers in Investigator Development and Community Engagement," PI Timothy F. Murphy, MD, I will leverage the skills and experiences I have gained in nearly 30 years of work in assessment and program evaluation. Going into the PhD program in educational psychology at the University at Buffalo, I had a great deal of experience in statistics and psychometric theory. To further build upon these skills, I enrolled in the quantitative methods track, completing such courses as quantitative research methods, regression analysis, path analysis, and multivariate analyses. I continued to develop skills in psychometric analysis, and, later in the PhD program, I completed a course in qualitative methods. Throughout my time in the program, I took consulting jobs related to survey development/ administration and statistical analysis. In addition, my experience with qualitative approaches to data collection helped me realize how important mixed methods are for triangulating findings. As a result of this new perspective, I used a qualitative analysis of interview data to help me address the research questions outlined in my dissertation.

As an assistant/associate professor at the University of West Georgia, I taught psychometric theory, research methods, and program evaluation. In addition, I worked on a departmental grant with funding from the DeWitt Wallace – Reader’s Digest fund. Part of the focus of the RFP was to better prepare school counselors in the areas of program evaluation and using assessments of student learning and success to inform improvements of student support programs across the P-12 landscape. I was charged with developing a course in program and evaluation and assessment specifically for school counselors. The result was a new course: Assessment and the Use of Data. While at West Georgia, I also served on the departmental assessment committee, through which we annually evaluated student progress and used the aggregate data for program improvement.

Through my work as a data manager and statistician at the Research Institute on Addictions, I worked on two multimillion-dollar grants: Women 2000 and Lives Across Time. I spent much time reading the literature in the areas of alcoholism, risky behavior, and sexual assault to “catch up” with research related to these projects, and I had two first-author publications during my time there. I was able to use my statistical, psychometric, and qualitative analysis skills to support numerous presentations, publications, and grant proposals. I also participated in trainings on more advanced statistical analysis procedures, including Structural Equation Modeling, Hierarchical Linear Modeling, and Power Analysis.

My true passion has always been higher education, specifically promoting effective instruction and helping students develop effective approaches to long-term learning. When I returned to the higher education environment as a research analyst in the Office of the Provost, I used a variety of data collection methods to support assessment and evaluation of both the student experience and various educational programs. Data sources included survey and questionnaire data, institutional systems data, and qualitative data from focus groups. I expanded my program evaluation skills through my roles as facilitator of student learning assessment, comprehensive program review, and program evaluator for the undergraduate general education program.

Over my career, I have also managed many individual and collaborative research projects, as well as initiatives related to my administrative duties. Based on these experiences, I have developed excellent project management skills, as evidenced by my role as co-chair of the Middle States Commission on Higher Education reaccreditation effort for both the 2014 and 2024 reviews. Further, since spring 2022, I have been the project lead for the implementation of the Brightspace learning management system, which will replace Blackboard in fall 2023. Reaccreditation and Brightspace implementation have been university-wide initiatives that require strict timelines and extensive coordination among constituents.

After returning to higher education administration, my only opportunity to serve as a program evaluator for funded projects was during my time in UB's Center for Educational Innovation. With my supervisor, I served as program evaluator for the KL2 training grant that was included as part of the proposal that established the Clinical and Translation al Science Institute. I also developed the program evaluation plan for a T35 training grant renewal (PI Dr. Timothy Murphy). Details of these awards are listed below:

Ongoing and recently completed projects that I would like to highlight include:

1KL2TR001413-01
Dubocovich (PI)
08/12/2015-07/31/2019
Engaging a Diverse Workforce of Translational Researchers

75490 – COEUS Proposal # 16031122
Murphy (PI)
09/15/2011-08/31/2021
Training the Next Generation of Physician Scientists

While I have limited experience as a program evaluator for funded projects, I have published results of program evaluations for educational programs and on usage and reliability/validity of various data collection methods. Several of these projects are listed below with citations in APA format:

1. **VanZile-Tamsen, C**. (2017). Using Rasch analysis to inform rating scale development. *Journal of Research in Higher Education,* DOI: 10.1007/s11162-017-9448-0.
2. Testa, M., Livingston, J. A., & **VanZile-Tamsen, C.** (2011). Advancing the study of violence against women with mixed methods. *Violence Against Women, 17*(2), 236-250.
3. Ahuna, K.H., Tinnesz, C. G., & **VanZile-Tamsen, C.** (2011). Methods of Inquiry: Using critical thinking to retain students. *Innovative Higher Education, 36* (4), 249-259.
4. Testa, M., **VanZile-Tamsen, C**., Livingston, J. A., & Koss, M. P. (2004). Assessing women's experiences of sexual aggression using the sexual experiences survey: Evidence for validity and implications for research. *Psychology of Women Quarterly, 28,* 256-265.

B. Positions, Scientific Appointments and Honors

Positions and Scientific Appointments

2021-present Associate Vice Provost, Curriculum, Assessment, and Teaching Transformation, University at Buffalo, Buffalo, NY
2021-present Adjunct Instructor, Learning and Instruction, University at Buffalo, Buffalo, NY
2019-present Adjunct Instructor, Social Sciences Interdisciplinary Programs, University at Buffalo, Buffalo, NY
2018-2021 Assistant Vice Provost, Office of Educational Effectiveness, University at Buffalo, Buffalo, NY

2016-2018	Assistant Director, Curriculum and Assessment, UB Curriculum, University at Buffalo, Buffalo, NY
2014-present	Adjunct Instructor, Counseling, School, and Educational Psychology, University at Buffalo, Buffalo, NY
2014-2018	Program Faculty, SUNY Center for Professional Development, Syracuse, NY
2014-2016	Associate Director, Center for Educational Innovation, University at Buffalo, Buffalo, NY
2012-2014	Associate Director, Office of Accreditation and Assessment, University at Buffalo, Buffalo, NY
2006-2012	Research Analyst, Office of Institutional Analysis, University at Buffalo, Buffalo, NY
2001-2006	Data Manager and Statistician, Research Institute on Addictions, University at Buffalo, Buffalo, NY
1996-2001	Assistant/Associate Professor, Counseling and Educational Psychology, University of West Georgia, Carrollton, GA

Other Experience and Professional Membership

2014-present	Peer Reviewer, Middle States Commission on Higher Education
2012-present	Co-Chair SUNY Council on Assessment
2012-present	Board Member, SUNY Council on Assessment
2012-present	Member, Assessment Network of New York
2012-15	Annual Conference Poster Coordinator, Northeastern Association of Institutional Research

Honors

2022	Plenary Speaker, First Annual Assessment Symposium, Stony Brook University
2015	Murray Straus Interpersonal Violence Original Research Award
2012	Institutional Research Leadership in Student Retention Award, sponsored by the Consortium for Student Retention Data Exchange

C. Contributions to Science

1. **Examination of Reliability/Validity and Usefulness of Approaches to Psychological Measurement, Data Collection, and Analysis.** Since the beginning of psychology as a field of study, psychologists grappled with the most effective methods to measure peoples' subjective perceptions, experiences, and memories. Over the past 150 years of research, human subjects have been concerned with this issue and have worked to improve the reliability, validity, and usefulness of psychological measures. This is an issue that I have been concerned with since my time as a PhD student attempting to measure metacognitive ability and motivation. Over the years, I have conducted and disseminated research on these topics. In addition to the article on Rasch analysis to examine the scaling of Likert-type measures (included above), I have several other products that have contributed to this area of study:

    a. Testa, M., **VanZile-Tamsen, C**., Livingston, J. A., & Koss, M. P. (2004). Assessing women's experiences of sexual aggression using the sexual experiences survey: Evidence for validity and implications for research. *Psychology of Women Quarterly, 28,* 256-265.
    b. Testa, M., Livingston, J. A., & **VanZile-Tamsen, C.** (2005). The impact of questionnaire administration mode on response rate and reporting of consensual and non-consensual sexual behavior. *Psychology of Women Quarterly, 29,* 345-352.
    c. **VanZile-Tamsen, C.** (2011, December). *What do I do with it now? Beginning and advanced analysis techniques for open-ended survey data.* Poster presented at the Annual Meeting of the Northeastern Association of Institutional Research, Boston, MA.
    d. **VanZile-Tamsen, C**., Testa, M., Harlow, L. L., & Livingston, J. A. (2006). A measurement model of women's behavioral risk taking. *Health Psychology, 25*, 249-254.

2. **Relationships Among Alcohol and Drug Use, Risky Behavior and Sexual Assault**. During my years at the Research Institute on Addictions, I was the Data Manager and Statistician on the Women 2000 project. On the project, we explored how childhood sexual abuse and substance use predicted risky behaviors related to HIV infection and sexual assault risk. However, we also explored how victimization occurs and is perceived within the context of intimated and long-term relationships, a thread that resulted from my qualitative analysis of interviews with women about their sexual assault histories. The Women 2000 project led to 14 publications, numerous presentations, and additional funded projects led by Testa and Livingston.

a. Testa, M., Livingston, J. A., **VanZile-Tamsen, C.**, & Frone, M. R. (2003). The role of women's substance use in vulnerability to forcible and incapacitated rape. *Journal of Studies on Alcohol, 64*, 756-764.
b. Testa, M., **VanZile-Tamsen, C.**, & Livingston, J. A. (2005). Childhood sexual abuse, relationship satisfaction, and sexual risk-taking in a community sample of women. *Journal of Consulting and Clinical Psychology, 73*, 1116-1124.
c. Testa, M., **VanZile-Tamsen, C.**, & Livingston, J. A. (2007). Prospective prediction of women's sexual victimization by intimate and nonintimate male perpetrators. *Journal of Consulting and Clinical Psychology, 75*, 52-60.
d. **VanZile-Tamsen, C.**, Testa, M., & Livingston, J. A. (2005). The impact of sexual assault history and relationship context on appraisal of and responses to acquaintance sexual assault risk. *Journal of Interpersonal Violence, 20,* 813-832.

3. **Program Evaluation and Statistical Analysis to Explore Learning and Health Disparities for Underrepresented Minorities.** My work in this area began as an evaluation of a learning skills development program. The findings of this evaluation were extremely interesting and showed that, while the program was overall effective in terms of promoting student success, it was most effective for students from underrepresented and/or disadvantaged populations. From this point on, I have always disaggregated data for any analyses that I do to allow for identification of inequities. This work has led to several publications and the Institutional Research Leadership in Student Retention Award mentioned above.

    a. Patterson, D.A., Ahuna, K.H., Tinnesz, C.G., & **VanZile-Tamsen, C**. (2014). Using self-regulated learning to increase Native American college retention. *Journal of College Student Retention: Research, Theory & Practice, 16*, 219-237.
    b. Patterson, D.A., **VanZile-Tamsen, C.**, Black, J., & Billiot, S. (2013). A comparison of self-reported physical health and health conditions of American Indian/Alaskan Natives to other college students. *Journal of Community Health, 38,* 1090-1097.
    c. Patterson, D.A., **VanZile-Tamsen, C.**, Black, J., Billiot, S., & Tovar, M. (2015). Impact of disability and other physical health issues on academic outcomes among American Indian and Alaskan Native college students: An exploratory analysis. *Journal of Social Work in Disability & Rehabilitation*.
    d. Fish, J., Livingston, J. A., **Van Zile-Tamsen, C.,** & Patterson, D. (2017). Victimization and substance use among Native American college students. *Journal of College Student Development, 58*.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/1vEh6oSuh-hAC/bibliography/public/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

BIOGRAPHICAL SKETCH

NAME: Wilding, Gregory E.

eRA COMMONS USER NAME: gewilding

POSITION TITLE: Professor; Chair, Department of Biostatistics

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
State University of New York at Brockport, Brockport, NY	BS	05/1996	Mathematics, Business Administration, Computer Science
University of Rochester, Rochester, NY	MA	05/1998	Statistics
University of Rochester, Rochester, NY	PhD	05/2003	Statistics

A. Personal Statement

I am a Tenured Full Professor in the Department of Biostatistics at the State University of New York at Buffalo (UB), housed within the School of Public Health and Health Professions, and have been a member of the faculty in the Department since its inception in 2002. In addition, I am Director of the Biostatistics, Epidemiology, and Research Design Core of the UB Clinical and Translational Research Center where I oversee many of the statistical efforts associated with interdisciplinary projects and develop educational initiatives around advanced research methods. I also hold courtesy appointments within the UB Jacobs School of Medicine and Biomedical Sciences and UB School of Nursing, am Associate Faculty within the UB Institute for Computational and Data Sciences, and am Research Associate within the Buffalo Center for Social Research. Beyond my work at UB, I serve as Professor of Biostatistics and Oncology at the Roswell Park Comprehensive Cancer Center's (RPCCC) Department of Biostatistics and Bioinformatics and as a Research Associate within the Department of Veterans Affairs. Over my 20-year career, I have developed extensive expertise in the design and analysis of clinical and non-clinical studies, based on both experimental and observational designs, and have participated in many aspects of numerous interdisciplinary research projects within and outside of UB resulting in over 250 published manuscripts. Many of these research projects have been grant funded and I have been a statistical co-investigator on over 45 current or past grants. I have also served on several scientific committees, data safety and monitoring boards, and internal review boards. In order to address barriers to clinical and translational science, I have made substantial contributions to the statistical methodological literature in the areas of clinical trial design, order-restricted inference, and exact inference approaches. I have been responsible for the statistical training of and have personally trained and mentored numerous graduate students, postgraduate researchers and faculty. Given me expertise and administrative roles, I am well positioned to provide the support needed to the researchers and pilot award recipients as described in this P50 grant application.

B. Positions, Scientific Appointments, and Honors

Positions & Scientific Appointments

2019-present Professor, Department of Medicine, University at Buffalo, Buffalo, NY
2019-present Associate Faculty, University at Buffalo Institute for Computational and Data Sciences, Buffalo, NY
2019-present Research Associate, Buffalo Center for Social Research, University at Buffalo, Buffalo, NY
2019-present Adjunct Professor, School of Nursing, University at Buffalo, Buffalo, NY
2017-2023 Chair, Department of Biostatistics, University at Buffalo, Buffalo, NY Buffalo, NY

2016-present	Director of Biostatistics, Epidemiology and Research Design Core of the Buffalo Clinical and Translational Research Center
2016-present	Research Associate, Department of Veterans Affairs
2016-2017	Interim Chair, Department of Biostatistics, University at Buffalo, Buffalo, NY Buffalo, NY
2015-present	Professor, Department of Biostatistics, University at Buffalo, Buffalo, NY
2015-present	Professor of Biostatistics and Oncology, Roswell Park Cancer Institute, Buffalo, NY
2012-2016	Co-Director of the Biostatistics Resource, Roswell Park Cancer Institute, Buffalo, NY
2009-2014	Adjunct Associate Professor, School of Nursing, University at Buffalo, Buffalo, NY
2009-2016	Vice Chair, Department of Biostatistics and Bioinformatics, Roswell Park Cancer Institute, Buffalo, NY
2009-2015	Associate Professor of Biostatistics and Oncology, Roswell Park Cancer Institute, Buffalo, NY
2009-2015	Associate Professor, Department of Biostatistics, University at Buffalo, Buffalo, NY
2009-2012	Director of the Biostatistics Resource, Roswell Park Cancer Institute, Buffalo, NY
2008-2009	Assistant Director of the Biostatistics Resource, Roswell Park Cancer Institute, Buffalo, NY
2007-2009	Assistant Professor of Biostatistics and Oncology, Roswell Park Cancer Institute, Buffalo, NY
2006-2009	Adjunct Assistant Professor, School of Nursing, University at Buffalo, Buffalo, NY
2005-2009	Assistant Chair, Department of Biostatistics, Roswell Park Cancer Institute, Buffalo, NY
2004-2005	Associate Biostatistics Consultant, Roswell Park Cancer Institute, Buffalo, NY
2003-2009	Assistant Professor, Department of Biostatistics, University at Buffalo, Buffalo, NY
2003	Research Assistant Professor, Department of Biostatistics, University at Buffalo, Buffalo, NY
2002-2005	Director of Statistical Consulting Laboratory, University at Buffalo, Buffalo, NY
2002-2003	Research Assistant Professor, Department of Social and Preventive Medicine, Division of Biostatistics, University at Buffalo, Buffalo, NY
1997-2002	Research Trainee, Department of Biostatistics, University of Rochester, Rochester, NY

Honors

2011	School of Public Health and Health Professions Outstanding Senior Researcher of the Year
2006	School of Public Health and Health Professions Outstanding Teacher of the Year

C. Contributions to Science

1. **Contributions in clinical trials.** I have participated in the design and conduct of clinical trials in a vast number of areas and settings. The designs of these studies have ranged from simple, single-center pilot studies to complex, multi-center adaptive trials. My role within these projects includes assistance in the selection and implementation of an efficient trial design, overseeing of clinical data management efforts, data safety and monitoring, execution of all planned statistical analyses, and assistance in dissemination of results. I am currently the statistical co-investigator on 6 grant funded trials.

   a. Holmes LC, Orom H, Lehman HK, Lampkin S, Halterman JS, Akiki V, Supernault-Sarker AA, Butler SB, Piechowski D, Sorrentino PM, Chen Z, **Wilding GE**. A pilot school-based health center intervention to improve asthma chronic care in high-poverty schools. J Asthma. 2022 Mar;59(3):523-535. PMID: 33322963

   b. Torka P, Patel P, Tan W, **Wilding GE**, Bhat SA, Czuczman MS, Lee KP, Deeb G, Neppalli V, Mavis C, Wallace P, Hernandez-Ilizaliturri FJ. A phase II trial of rituximab combined with pegfilgrastim in patients with indolent B-cell non-hodgkin lymphoma. Clin Lymphoma Myeloma Leuk. 2018 Jan;18(1):e51-e60. PMID: 29233743

   c. Chowriappa A, Raza SJ, Fazili A, Field E, Malito C, Samarasekera D, Shi Y, Ahmed K, **Wilding GE**, Kaouk J, Eun DD, Ghazi A, Peabody JO, Kesavadas T, Mohler JL, Guru KA. Augmented-reality-based skills training for robot-assisted urethrovesical anastomosis: a multi-institutional randomized controlled trial. BJU Int. 2015 Feb;115(2):336-45. PMID: 24612471

d. Cummings JJ, Gerday E, Minton S, Katheria A, Albert G, Flores-Torres J, Famuyide M, Lampland A, Guthrie S, Kuehn D, Weitkamp J-H, Fort P, Abu Jawdeh EG, Ryan RM, Martin GC, Swanson JR, Mulrooney N, Eyal F, Gerstmann D, Kumar P, **Wilding GE**, Egan EA, AERO-02 STUDY INVESTIGATORS. Aerosolized calfactant for newborns with respiratory distress: a randomized trial. Pediatrics. 2020 Nov;146(5):e20193967. PMID: 33060258

2. **Contributions in longitudinal designs.** Much of my work has required the use of advanced longitudinal statistical models to address meaningful scientific questions, including the use of generalized estimating equations, multivariate marginal models, linear mixed models, and generalized mixed linear models. This work has been in collaboration with both basic science and clinical research faculty.

   a. Fuchs T, Wojcik C, **Wilding GE**, Pol J, Dwyer MG, Weinstock-Guttman B, Zivadinov R, Benedict RHB. Trait conscientiousness predicts rate of longitudinal SDMT decline in multiple sclerosis. Mult Scler. 2020 Feb;26(2):245-252. PMID: 30615562

   b. Abu Lehyah NAA, Hasan AA, Juneau JN, Al Jammal MA, Jaber GA, **Wilding GE**, Roberts KD, Guthrie SO. Implementation of surfactant administration through laryngeal or supraglottic airways (SALSA): a Jordanian NICU's journey to improve surfactant administration. Children (Basel). 2022 Jul 30;9(8):1147. PMCID: PMC9406484

   c. Szigeti K, Ihnatovych I, Birkaya B, Chen Z, Ouf A, Indurthi DC, Bard JE, Kann J, Adams A, Chaves L, Sule N, Reisch JS, Pavlik V, Benedict RHB, Auerbach A, **Wilding GE**. CHRFAM7A: A human specific fusion gene, accounts for the translational gap for cholinergic strategies in Alzheimer's disease. EBioMedicine. 2020 Sep;59:102892. PMCID: PMC7452451

3. **Methodological contributions.** A large portion of my interdisciplinary research is in the areas of clinical trials and pre-clinical research where I have made substantial contributions in study design and analysis. Motivated by the shortcomings of available statistical methods I have encountered, I have dedicated a considerable amount of effort to the development of analysis methods and innovative study designs. The statistical research topics have included the modeling of the area under the curve, often used as a measure of total exposure when working with outcomes such as drug concentration in the study of pharmacokinetics, early phase clinical trial design, and exact statistical inference.

   a. **Wilding GE**, Shan G, Hutson AD. Exact two-stage designs for phase II activity trials with rank-based endpoints. Contemp Clin Trials. 2012 Mar;33(2):332-41. PMID: 22074983

   b. **Wilding GE**, Consiglio JD, Shan G. Exact approaches for testing hypotheses based on the intra-class kappa coefficient. Stat Med. 2014 Jul 30;33(17):2998-3012. PMID: 24634280

   c. Chandrasekhar R, Shi Y, Hutson AD, **Wilding GE**. A Novel Approach to Testing for Average Bioequivalence Based on Modeling the Within-Period Dependence Structure. J Biopharm Stat. 2015;25(6):1320-38. PMID: 25671781

Complete List of Publishing Work in MyBibliography:
https://pubmed.ncbi.nlm.nih.gov/?term=((((Wilding+G%5BAuthor%5D)+OR+Wilding%2C+Gregory%5BAuthor%5D)+OR+Wilding+GE%5BAuthor%5D)+OR+Wilding%2C+Gregory+E%5BAuthor%5D)

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Research Foundation for SUNY on behalf of U. at Buffalo
UEI:	LMCJKRFW5R81
Street1*:	The UB Commons
Street2:	520 Lee Entrance, Suite 211
City*:	Amherst
County:	Erie
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14228-2567
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB Clinical and Translational Research Center
UEI:	
Street1*:	875 Ellicott Street
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14203-1034
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Jacobs School of Medicine and Biomedical Sciences
UEI:
Street1*: 955 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1034
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Public Health and Health Professions
UEI:
Street1*: 3435 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3099
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 4

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Nursing
UEI:
Street1*: 3435 Main Street- Wende Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3010
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 5

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Architecture and Planning
UEI:
Street1*: 3435 Main Street- Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3015
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 6

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Community Health Equity Research Institute
UEI:
Street1*: 875 Ellicott Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1070
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 7

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Buffalo Center for Health Equity
UEI:
Street1*: 257 West Genesee Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14202-2657
Project/Performance Site Congressional District*: NY-026

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ● **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00008824

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Abstract.pdf
8. Project Narrative*	Narrative.pdf
9. Bibliography & References Cited	Bibliography_Overall.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources.pdf
11.Equipment	Equipment.pdf
12. Other Attachments	UB_VPHS_effort_attestation.pdf Special_Eligibility_Requirements.pdf

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

Buffalo, New York, the second largest city in New York State (population 278,349), has a diverse population, including 37% African American and 14% Latinx. One of the most pressing problems in metropolitan Buffalo is race-based health inequities, a condition shared with many American metropolitan areas. The life expectancy of African American residents of Buffalo is 10 to 12 years shorter compared to White residents of Buffalo. African Americans are 300% more likely to have chronic, often preventable, diseases than Whites who live in Buffalo. In response to this crisis, in 2014, a group of visionary community leaders created the African American Health Equity Task Force, which includes leaders and stakeholders from multiple sectors of the Buffalo community, including faith leaders, community non-profits, healthcare providers, payers, University at Buffalo (UB) faculty and more. The Task Force has met monthly since 2015 and led to the formation of three new organizations, including the UB Community Health Equity Research Institute (2019), the community-based Buffalo Center for Health Equity (2019) and the Erie County Office of Health Equity (2021). Leaders of these three organizations continue to meet monthly as part of the Task Force. This **community-university-government partnership** has enormous reach and influence throughout the community, positioning us to disseminate research findings and work with policy makers and community stakeholders to promote sustainable community- and system-level change. **The mission of our NIMHD Center of Excellence in Investigator Development and Community Engagement is to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community.** The Center of Excellence will be embedded in the UB Community Health Equity Research Institute, which includes faculty from all 12 UB schools, creating a transdisciplinary framework that cuts across scientific and organizational silos to integrate disciplines to address the full range of social determinants of health and to mentor early-career investigators in research in health disparities. Our Center of Excellence will inspire, train, and mentor a new generation of scientists from diverse backgrounds and disciplines to perform innovative research in health disparities and advance their careers (Aim 1). We will nurture our enduring community-university partnerships to perform transdisciplinary research to develop and test innovative solutions to end race-based health inequities in Buffalo (Aim 2). Finally, we will advance equitable collaborations with community partners to translate our research into sustainable, community and system-level changes toward eliminating race-based health inequities in Buffalo (Aim 3). Our enduring community-university-government partnership a strong foundation for an NIMHD Center of Excellence will be an exceptional advance in our environment to train and mentor a new generation of researchers to perform research that will create sustained improvements in health outcomes in African American communities in Buffalo and the nation.

Buffalo, New York, the second largest city in New York State (population 278,349), experiences disturbing race-based health inequities that shorten the lifespan and reduce quality of life for people of color who reside in predominantly African American neighborhoods on the East Side of Buffalo. Community leaders and stakeholders from multiple sectors of the Buffalo community have created an enduring **community-university-government partnership** that has enormous reach and influence throughout the community, positioning us to disseminate research findings to promote sustainable system-level change. The goal of our University at Buffalo NIMHD Center of Excellence in Investigator Development and Community Engagement is to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community.

FACILITIES & OTHER RESOURCES

University at Buffalo

The University at Buffalo (UB) is the flagship institution in the State University of New York (SUNY) System. It is a research-intensive institution and the largest and most comprehensive campus in the 64-campus SUNY System. The University at Buffalo is comprised of three campuses – North Campus, South Campus and the Buffalo Niagara Medical Campus in downtown Buffalo – includes six health sciences schools (Jacobs School of Medicine and Biomedical Sciences, School of Public Health and Health Professions, School of Dental Medicine, School of Nursing, School of Pharmacy and Pharmaceutical Sciences, and School of Social Work), School of Architecture and Planning, College of Arts and Sciences, School of Engineering and Applied Sciences, School of Law, School of Management, and Graduate School of Education.

We envision that early-career investigators who will be mentored and trained in our NIMHD Center of Excellence in Investigator Development and Community Engagement will be faculty and postdoctoral fellows based in any of the 12 UB schools noted above. For this reason, we include an overview of the extensive resources at UB to support research of many kinds, with emphasis on those that are most likely to interface with the community. In addition to research centers and core facilities at UB, Roswell Park Comprehensive Cancer Center has outstanding core services that are available to UB researchers. Roswell Park is located on the Buffalo Niagara Medical Campus and is a close partner with UB in research, education and clinical care activities.

Resources and Research Centers (additional centers based in individual schools are noted under selected schools below. Note that centers based in individual schools are available to all UB researchers).

- UB Community Health Equity Research Institute brings together 12 UB schools (Architecture and Planning, Arts and Sciences, Dental Medicine, Education, Engineering, Jacobs School of Medicine and Biomedical Sciences, Law, Management, Nursing, Pharmacy and Pharmaceutical Sciences, Public Health and Health Professions, and Social Work) and community stakeholders for a mission to perform research to advance understanding of the root causes of health disparities and develop and test innovative solutions to eliminate health inequities. The ultimate goal/vision of the institute is to ensure that wellness and social well-being become a reality for all people in Buffalo, including people of color residing in underserved neighborhoods and who are more likely to have serious, chronic and often preventable diseases, as well as significantly higher mortality rates. This Institute is described in detail in the proposal.
    - Center for Urban Studies is a research and service entity that is embedded in the Community Health Equity Research Institute that seeks solutions to the problems facing cities and metropolitan regions. The Center works to build healthy communities and to create just cities and metropolitan regions. The intent is to build vibrant neighborhoods based on community control, participatory democracy, and cooperative economics that are anchored in people-centered urban centers based on social, economic, political, cultural and racial justice. To achieve this goal the UB Center for Urban Studies uses a prefigurative neighborhood planning strategy, engages in radical community development, and works with other groups and organizations to transform underdeveloped and marginalized neighborhoods into vibrant, healthy communities that are controlled by its residents.
- Clinical and Translational Science Institute, funded by an NIH Clinical and Translational Science Award, provides expert, broad-based support to investigators at the UB and partner Buffalo Translational Consortium institutions. Core services include:
    - A centralized university-wide Clinical Research Office with support for clinical research, including regulatory support, IRB pre-reviews, assistance with designing clinical trial recruitment plans and conducting studies
    - Biostatistics, Epidemiology and Research Design (BERD) core services
    - Community Engagement Team to engage community members as participants in research projects and develop and implement innovative recruitment plans
    - Comprehensive education, training and career development oportunities with an extensive range of seminars, workshops, certificate and degree-granting programs in the broad area of clinical and translational research
    - Translational Imaging Center that includes a 3T MRI and a PET CT for humans and large animals, and a 9.4 Tesla MRI for small animals, in addition to expert consultation, collaboration and assistance

- Biomedical Informatics Core for collaboration and support for research database creation, biomedical informatics projects and high-performance computing
- Laboratory Core Facilities navigation to assist investigators in identifying the best core among a robust array of core facilities to support their research activities

The hub of the CTSI is the UB Clinical and Translational Research Center (CTRC), a 170,000 foot^2 modern research building that opened in 2012. The CTRC includes the administrative offices and core functions of the CTSI; a Clinical Research Center with 7 examination rooms for clinical trial visits and support for blood drawing, specimen collection and laboratory processing of samples; open architecture, state-of-the-art laboratories that house 35 principal investigators with translational research programs; an AAALAC-certified 20,000 foot^2 Laboratory Animal Facility for small and large animals, including a transgenic mouse facility; a biorepository and specimen processing laboratory with the capacity to store two million samples with associated informatics; the Translational Imaging Center devoted exclusively to research; seminar and educational facilities with modern audiovisual infrastructure.

- Institute for Healthcare Informatics (IHI) is a secure, HIPAA-compliant academic data center that opened in 2012. Its servers are in the Center for Computational Research. The IHI provides a secure environment where healthcare data are stored, aggregated and analyzed. The IHI houses approximately 700,000 fully identified patient records (UBMD practice plan and Kaleida Health System) and limited-data sets of claims encompassing 1.5 million individuals. Fully identified Kaleida Health patient records (~1 million patients) are being moved into the IHI. The IHI hosts an i2b2 dashboard for feasibility studies and cohort identification, is a CTSA Accrual to Clinical Trials (ACT) site and partners with TriNetX to provide access to industry-funded clinical trials. Present production data capacity is 14.1 terabytes of encrypted storage with clustered servers with the ability to scale as needs grow. Clinical data are protected by employing multilayered security, including a scalable, virtual machine environment.

- Clinical Research Office supports investigators and their study staff to create, establish and manage research that advances our understanding of human health and behavior. The CRO provides the following services for the investigator:
  - IRB and Regulatory Document Preparation
  - Protocol Development and Review
  - Contracts Negotiation
  - Budget Negotiation
  - Accounts Receivable/Accounts Payable Set-up, Maintenance and Reconciliation
  - Research Subject Advocacy
  - Coverage Analysis Review
  - Clinical Research Coordinator Support (if requested)
  - Navigation of Available University Support Services

- Sponsored Projects Services within the UB Office of the Vice President for Research and Economic Development, is dedicated to supporting UB faculty and staff in their efforts to seek out and secure external awards for programs of research, scholarly and creative activities, education and training, and public service. Further, Sponsored Projects supports faculty and staff in their efforts to manage external award funds effectively and prudently to ensure that all sponsor and University commitments and expectations are met. The Sponsored Projects web site provides several mechanisms for faculty and staff to obtain information about funding opportunities, including a searchable database that can be searched by program type, deadline, discipline, and title keywords. A personalized funding search service is available to UB faculty and staff upon request. Sponsored Projects staff work closely with faculty in the pre-award and post-award phases of their extramurally funded research.

- Office of Research Compliance oversees policies and programs including financial conflicts of interest; responsible conduct of research, intellectual and creative activity; and export controls. It interacts with federal, state and other regulatory agencies and works collaboratively with UB safety offices. The Office of Research Compliance provides the following services:
  - AAHRPP accredited Institutional Review Board
  - CITI Training
  - Responsible Conduct in Research Training
  - Institutional Animal Care and Use Committee

- Export Controls

- Institute for Artificial Intelligence and Data Science (IAD) brings together researchers, labs, institutes, and centers of excellence at the University at Buffalo that are focused on advancements in AI, data science, computational science and related areas of research to tackle these complex problems. The Institute include faculty with expertise who focus on the following activities:
  - Advance the disciplinary core of AI and Data Science,
  - Identify cross-cutting applications in other disciplines,
  - Study social and cultural implications and assume leadership in the formulation of policies for ethical and legal considerations,
  - Design innovative educational programs and skills training mechanisms to prepare students and retool the workforce for the era and big data and AI,
  - Develop strategic partnerships with industry and government,
  - Evolve training ecosystems for workforce development.

- Buffalo Institute for Genomics (BIG) & Data Analytics provides informatics and biomedical expertise to advance genomic medicine. A $100 million New York State grant to the University at Buffalo and the New York Genome Center in New York City created this unique partnership to make the state a leader in the field. BIG is also a regional asset, offering operational resources to industry partners, helping them in innovative practices and processes as well as creating jobs.

- Center for Computational Research (CCR) is a leading academic supercomputing facility that maintains a high-performance computing (HPC) environment, high-end visualization laboratories, and corresponding support staff with expertise in advanced computing, modeling and simulation, and data analytics dedicated to support Buffalo Translational Consortium (BTC) researchers. Together these resources support CCR's core mission of enabling research in Western New York providing high-tech workforce training, and fostering economic development and job creation within Western New York and New York State. The Center's computing facilities include a Linux cluster with more than 13,000 processor cores connected via a high-speed QDR Infiniband network and a 3,000 core Linux cluster that is dedicated to support economic development through outreach to industry. In addition to providing access to state-of-the-art computing and visualization resources, CCR's staff of computational scientists and software engineers provide researchers and industrial partners with support for modeling and simulation, software development, bioinformatics, and data analytics.

- Institute for Lasers, Photonics and Biophotonics focuses on Photonics, the science and technology based on light, which is projected to play a dominant role in this century-impacting communication, information technology and healthcare, as well as consumer commodities. The Institute's objective is to contribute to the economic development of the region.

- Institute on Innovative Aging Policy and Practice promotes aging-related research, scholarship, learning and service concerning care for older persons, particularly those most vulnerable and oppressed. The Institute is housed within the Buffalo Center for Social Research and is dedicated to the health, well-being and independence of older adults.

- Jacobs Neurological Institute is made up of a preeminent team of neurologists and other healthcare professionals who are part of the UB Department of Neurology. The Institute integrates innovative, compassionate patient care with interdisciplinary neurological research.

- National Center for Ontological Research (NCOR) has a goal of advancing the quality of ontological research and development and of establishing tools and measures for ontology evaluation and quality assurance. NCOR serves as a vehicle to coordinate, enhance, publicize, and seek funding for ontological research activities. It provides researchers working in ontology-related areas with specialized support in seeking external funding and in assembling collaborative, interdisciplinary teams both nationally and internationally. It provides consulting services for ontology projects especially in the defense and security fields and in healthcare and biomedical informatics.

- UB Center for Advanced Technology in Big Data and Health Sciences, sponsored by Empire State Development's Division of Science, Technology and Innovation, is one of 15 such designated Centers in New York State dedicated to leveraging University resources to drive company growth. The Center is focused

on the intersection of big data and health sciences, particularly as it relates to drug development, medical devices, diagnostic tools and healthcare IT.

- UB Genome, Environment and Microbiome Community of Excellence (GEM) looks to advance understanding of the genome, microbiome and their interaction with the environment, and uses this knowledge to benefit humanity in a just, broad-based and responsible manner. GEM facilitates interactions among academia to promote innovative approaches to important problems through cross-disciplinary research within the life sciences and between the life sciences, social sciences and the arts. Through outreach and engagement related to its research, GEM strives to become a national model for increasing literacy in these areas.
- Community for Global Health Equity supports those who most influence global health—leaders, organizations and policy makers who can affect systemic change and community members around the world who can inspire, promote, and implement solutions in their respective neighborhoods. The community brings together scholars in health sciences and Architecture, Planning, Engineering, and other cross-synergizing disciplines (APEX) to:
    - advance foundational science to develop innovative, low-cost solutions to improve health equity
    - develop innovative solutions to overcome socio-cultural barriers to optimal health and well-being
    - build and sustain relationships with and contribute critical guidance to policy-making organizations to improve global health equity
    - improve the dissemination of equity-promoting practices of implementation organizations
    - demonstrate impact through projects that improve the health and well-being of target communities
    - train students to develop the expertise to work effectively in interdisciplinary teams and to contribute to research, engagement and implementation activities that advance global health equity
- UB Microbiome Center works with faculty, researchers, students, and experts worldwide to understand the impact of microbiomes by studying the microbiome in health and disease, enhancing our understanding of the challenges, and refining our applications of the new knowledge.
- BioXFEL (Biology with X-ray Free Electron Lasers) is a Science and Technology Center supported by a $25 million National Science Foundation grant to the University at Buffalo and Hauptman-Woodward Research Institute. Headquartered in Buffalo, BioXFEL is a collaboration of eight research universities to hold images of protein translation through conformational states filmed by the Stanford Accelerator. The center focuses on developing new X-ray bioimaging techniques to analyze new molecular targets for drug discovery.

Laboratory Core Facilities

- **Genomics and Proteomics**
    - DNA Sequencing Lab (Roswell Park) is a component of the Genomics Shared Resource, a shared resource facility at Roswell Park Cancer Comprehensive Center. Through state-of-the-art biomolecular instrumentation and techniques, it provides services including cycle sequencing of DNA samples and primers, purification of reacted samples, sequencing run, and analysis and editing of data.
    - Genomic Shared Resource (Roswell Park) provides investigators a full spectrum of services for parallel analyses of genomes and their expression. Applications include Comparative Genomic Hybridization (CGH) and global gene expressions profiling. The facility maintains and provides a screening and clone characterization service for nine large insert genomic BAC & PAC libraries for human, mouse, rat, and S. Pombe as a resource for investigators.
    - Next Generation Sequencing and Expression Core (New York State Center of Excellence in Bioinformatics and Life Sciences) offers high-throughput, next-generation sequencing on two illumine HiSeq2500 and MiSeq platforms. The expertise in whole-genome, exome, epigenetic and microbiome sequencing in conjunction with a team of bioinformaticists helps facilitate rapid analysis and algorithm deployment, data storage and management. The facility also provides gene expression analysis services on Affymetrix platforms, including 3'-expression, miRNA, exon and gene arrays.
    - UB's Genomics & Bioinformatics Core (GBC) offers high-throughput, next-generation sequencing on two illumine HiSeq2500 and MiSeq platforms. The expertise in whole-genome, exome, epigenetic and microbiome sequencing in conjunction with a team of bioinformaticists helps facilitate rapid analysis and algorithm deployment, data storage and management. The facility also provides gene expression

analysis services on Affymetrix platforms, including 3'-expression, miRNA, exon and gene arrays. GBC has a long-standing track record in next generation sequencing technology and provides high-throughput massively parallel sequencing and bioinformatics expertise and services to university faculty, industry and other research institutions. This includes a comprehensive suite of sequencing services such as exome, transcriptome, microbiome, and epigenome sequencing. The GBC has several Illumina next generation platforms including a NovaSeq6000, a NextSeq500 and two MiSeqs for all library sequencing needs. In addition, the GBC has the 10X Genomics Chromium Platform for single cell transcriptomics, single cell ATACseq and immunogenomic identification from cultured cells or native tissues. Other on site equipment for the generation of NGS libraries include the BluePippin gel purification system, Advanced Analytical's Fragment Analyzer, the BioRad QX100 and QX200 Droplet Digital PCR Machines, QIAsymphony SP robot for nucleic acid extraction, a Qiagen Q48 pyrosequencer and a Diagenode SX-8G IP-Star Compact system for performing automated ChIP. Staffed with three bench scientists and three computational scientists, the core has extensive expertise in genomic sequencing and bioinformatic analyses. The Center for Computational Research (CCR) works synergistically with the GBC in support of the core's data analytics and data management needs. Data is transferred directly from the sequencers to CCR resources in real time, reducing processing time and enabling direct access to high-performance computing resources. The genomic data produced is also managed and backed-up by CCR staff, allowing researchers to focus on the biology of their work, rather than server and data maintenance.

- Proteomics/Mass Spectrometry Core (New York State Center of Excellence in Bioinformatics and Life Sciences) focuses on ultra-sensitive quantification of small-molecule analytes, comprehensive protein expression profiling and differential proteome analysis, and ultra-sensitive quantification of proteins/peptides. The core facility identifies proteins in cell or tissue extracts using several different liquid chromatography/mass spectrometry based approaches. The UB Proteomics & Bioanalysis Core (PBC) specializes in proteomics, LC/MS (liquid chromatography–mass spectrometry) and bioinformatics. The core houses three mass spectrometers: 1x high-resolution Thermo Lumos ETD, 2x Thermo Quantiva triple-quad; eight liquid chromatography systems; high flow fractionation systems; micro-flow LC and nano-LC ultra-high-pressure systems. The PBC provides collaborative services in: quantitative proteomics and biomarker discovery (quantification of >5000 proteins in clinical or pharmaceutical samples); large-scale protein or proteome identification; identification and localization of post-translation modifications on proteins; high-throughput quantification of specific protein markers in large-scale analysis; LC/MS-based biological and pharmaceutical analysis (regulated or unregulated). The facility includes a well-equipped wet-lab devoted to cell culture, biochemistry experiments (for Western-blotting, electrophoresis, ELISA, etc.), column packing and sample preparation for quantitative analysis.

- **Laboratory Animal Core Facilities**
  - Comparative Medicine-Laboratory Animal Facility (CM-LAF) is a centralized service organization responsible for the animal care, research and education across the University at Buffalo. Through its administrative and veterinary services, the CM-LAF assures that healthy animals are available for use by faculty members who have received approval to perform research, testing or education studies on animal subjects. The facility includes animal housing for more than 13 species of research animals; high-security, barrier housing for pathogen-free animals and for genetically altered animals; procedure rooms, operating theaters and surgical training areas; comprehensive equipment for gas anesthesia and anesthesia monitoring; radiological suite for diagnostic X-ray; pharmacy for sourcing and dispensing routine preparations and scheduled drugs; clinical pathology laboratory for blood counts, biochemistry and other diagnostic tests; and air-conditioned vehicle for animal transport.
  - Gene Targeting and Transgenic Facility (GeTT) (Roswell Park) provides services to modify the murine genome by transgenic approaches for systematic dissection of the genetic, molecular, cellular and physiological mechanisms underlying complex biological processes. GeTT also assists in the development of unique mouse models that contribute to understanding imprinting and its role in cancer, regulation of important genes and two transgenic models that mimic chromosome rearrangements associated with specific human cancer. GeTT has the resources and skills necessary to construct mice with defined mutations at specific locations of the mouse genome by in vitro manipulation of embryonic stem (ES) cells by blastocyst injection of altered ES cells.

- Laboratory Animal Resources (LAR) (Roswell Park) is responsible for the support of biomedical research by promoting the human care of laboratory animals at Roswell Park Comprehensive Cancer Center. The LAR provides the entire spectrum of animal-related research services including specialized animal husbandry, veterinary medical care, diagnostic services, irradiation services, imaging resources, and training of investigators and laboratory personnel.

- **Biorepositories and Tissue Specimens**
  - Clinical and Translational Research Center (CTRC) Biobank includes a biobank facility capable of storing 2 million specimens, as equipped using institutional resources. The service and specimens are available to Buffalo Translational Consortium investigators. The CTRC biobank has implemented informatics and annotation using principled biomedical ontologies and is designed to integrate with the Roswell Park and Department of Social and Preventive Medicine biorepositories.
  - Data Bank and BioRepository (DBBR) (Roswell Park) collects and provides de-identified biospecimens and associated epidemiological and clinical data to meet the scientific needs of investigators. The DBBR strives to provide specimens that are rigorously collected, processed and stored so the integrity of potential analytes will be consistent across all patients and controls. The DBBR team works integrally with investigators to hone their research concepts and identify best available biospecimen and data sources to support their research needs.
  - Department of Social and Preventive Medicine Biological Specimen Bank houses specimens collected as part of epidemiological studies and clinical trials conducted in the department. A complex, secure computerized mapping system tracks the specimens and a sophisticated back-up system maintains integrity. The Department of Social and Preventive Medicine bio-bank currently houses over 1 million samples from over 25,000 participants, which in conjunction with the specimen bank at Roswell Park Comprehensive Cancer Center and the Clinical and Translational Research Center provides a novel resource for translational science.
  - Pathology Network Shared Resource (Roswell Park) provides human specimens and laboratory services for basic and translational research to further understanding of the cellular and molecular pathogenesis of human cancers. The overall mission is to facilitate access to human tissue for investigators with an emphasis on translational efforts.

- **Immunology and Histology Core Facilities**
  - Flow Cytometry and Cell Sorting provides training and consultation services for researchers whose work involves flow cytometry, confocal microscopy and gel-documentation. The facility hosts two analytical flow cytometers and a state of art high-speed cell sorter. The analytical instruments include a BD FACS Calibur four-color and a BD FACScan three-color system. The FACS Aria high-speed cell sorter can analyze and select cells based on up to seven fluorescent colors. Multiplex cytokine analysis is performed by the BD FACSArray Bioanalyzer utilizing the cytometric bead array technique.
  - Flow and Image Cytometry Shared Resource (FICSR) (Roswell Park) provides advanced flow cytometric and morphology service utilizing state-of-the-art technology and an extensive computer network that has been assembled into a user-friendly and cost-effective environment. FICSR provides multiparameter flow cytometry, encompassing analytical, sorting and Luminex services; Confocal, Live Cell and ImageStream imaging services; and instruction and technical support as required by investigators.
  - Histology Service Laboratory is equipped to process tissue for paraffin embedding, section paraffin blocks, and make available a wide variety of routine and special stains. It has two cryostats for sectioning frozen tissue specimens to facilitate rapid diagnosis, lipid and enzyme demonstration, some immunohistochemical techniques or immunofluorescence work. In addition, it has a JB-4 microtome for cutting methacrylate embedded tissues but does not currently provide services with this piece of equipment. Since 1980, the Histopathology Lab has served the University at Buffalo and Western New York as a full-service histology lab available to students, faculty, researchers, and clinicians.

- **Microscopy and Imaging Facilities**
  - Center for Biomedical Imaging (CBI) is a comprehensive core facility of the UB Clinical and Translational Science Institute. Its state-of-the-art services and common platform for storing, analyzing and sharing

imaging data (3T MRI for human and large animals, 9.4T MRI for small animals, and PET/CT scanners) advances clinical and preclinical research. CBI team expertise is available for clinical and translational researchers seeking to incorporate standard and advanced imaging into protocols. The center is dedicated to providing innovative, affordable, invasive and noninvasive, high-resolution, in vivo and ex vivo imaging and support to UB investigators and external collaborators.

- o Confocal Microscopy and Cellular Imaging Facility provides Zeiss LSM-510 Meta NLO laser scanning confocal microscope services with the capability of simultaneous imaging of multiple-emission wavelengths, transmitted light imaging and multiphoton capability through the addition of a Coherent Chameleon Ultra II laser. Zeiss Axio Observer and Axioimager wide-field fluorescent microscopes are available for bright field, DIC and phase contrast imaging with cooled-CCD and color cameras.
- o Electron Microscopy Laboratory provided by the Department of Pathology and Anatomical Sciences, allows faculty, trainees, students and other researchers to bring their work requiring technology for high resolution thin section work and biological specimen preparation. The facility is available to assist investigators in routine sample preparation for transmission and electron microscopy analysis, for training, and for project consultation.
- o Scanning Transmission X-ray Microscopy provided by the School of Dental Medicine to include secondary electron imaging with magnification up to 100,000X and spatial resolution better than 50 å; backscattered electron imaging of chemical phase difference; qualitative and quantitative elemental analysis with EDS; x-ray imaging—elemental line scans and maps.
- o Small Animal Bio-Imaging Resource (Roswell Park) provides the necessary intellectual and physical resources relating to non-invasive in vivo in small animal models of cancer. This resource provides insight into various biological processes involved in disease and facilitate evaluation of experimental therapeutics and enables translation of imaging techniques evaluated in preclinical models to improve disease detection and monitoring of therapeutic response in the clinical setting.

- **Drug Development and Pharmacology**
  - o cGMP (Center for Immunotherapy Good Manufacturing Practices Therapeutic Cell Production) Facility consists of a class 100,000 anteroom (gowning and storage) and class 10,000 cell processing room (manufacture of cell therapy products for Phase I and Phase II clinical trials).
  - o Small Molecule Screening Shared Resource (SMSR) (Roswell Park) provides investigators with the possibility of screening chemical libraries in a variety of readout systems for new prospective diagnostic and therapeutic compounds and research tools. Researchers can get assistance with the design and the execution of chemical screenings. SMSR's collection of chemicals totals more than 110,000 compounds.
  - o Toxicology Research Center provides expertise in toxicology for basic and applied research projects. The facility maintains an analytical toxicology laboratory and offers a wide variety of analytical techniques to solve complicated research problems. This multiuser facility houses instrumentation for conducting cellular, biochemical and molecular studies, and concentrates on new method development and sample analysis.
  - o Translational Pharmacology Research Core (TPRC) (New York State Center of Excellence in Bioinformatics and Life Sciences) is designed to facilitate and expedite the translation of pre-clinical and development research into approved drugs with real-world benefits. TPRC is designed to foster collaboration and advance innovation at multiple stages of drug development. The core's work is wide-ranging but emphasizes oncology, neurology, infectious disease, cardiovascular disease, and inflammation and immunosuppression.
  - o X-ray Crystallography Core/High-Throughput Crystal Screening Center (HTCSC) (Hauptman Woodward Medical Research Institute) is a facility used to identify crystallization conditions for biological macromolecules. It makes use of automated liquid handling imaging systems coordinated through a LIMS/database to quickly set up and record the outcomes of 1,536 unique crystallization screening experiments.

- **Stem Cell Core Facilities**

- Induced Pluripotent Stem Cell Generation facility helps investigators generate induced pluripotent stem cells from human skin fibroblasts using lentiviral vectors delivering five reprogramming factors. It reprograms cells to iPSC and perform characterization by PCR and immunostaining, and return the iPSC lines. The facility also trains users to develop iPSC lines for basic and translational research.
- Stem Cell Culture, Banking and Training maintains and banks stem cells and provides stem cells and training to researchers interested in using them in research projects. The facility offers feeder cell isolation and propagation; expansion and banking of stem cell lines and culturing of stem cells; provision of pluripotent stem cells to particular cell types; hoods, incubators and certified reagents for stem cell culturing; and consultations and training courses.
- Stem Cell Engraftment and In Vivo Analysis facility analyzes the engraftment of a variety of stem cells in vivo, the effects of genetic modification of stem cells on engraftment and stem cell function, and the behavioral consequences of neural engraftment.
- Stem Cell Sequencing/Epigenomics Analysis facility is a resource for epigenomic analysis of stem cells that function interactively with other the other stem cell facilities to characterize stem cells and their differentiated progeny. The goals of the facility are to characterize the transcriptome and epigenome of all stem cell types and their derived lineages and provide experimental and computational support for investigator-initiated genomic expression or epigenetic experiments.

Jacobs School of Medicine and Biomedical Sciences

Founded in 1846, the Jacobs School of Medicine and Biomedical Sciences is one of the oldest medical schools in the United States and is the only medical school in Buffalo. It builds upon its proud legacy of teaching, patient care and scientific discovery. Its mission is to advance health and wellness across the life span for the people of New York and the world through the education of tomorrow's leaders in healthcare and biomedical sciences, innovative research and outstanding clinical care. Included within the Jacobs School are the 26 departments: anesthesiology, biochemistry, biomedical engineering, biomedical informatics, biotechnical and clinical laboratory science, emergency medicine, family medicine, medicine, microbiology and immunology, neurology, neurosurgery, nuclear medicine, obstetrics and gynecology, ophthalmology, orthopaedics, otolaryngology, pathology and anatomical sciences, pediatrics, pharmacology and toxicology, physiology and biophysics, psychiatry, radiation oncology, radiology, structural biology, surgery, and urology. The Jacobs School has a unique consortium of affiliated teaching hospitals and health care systems – Kaleida Health (Buffalo General Medical Center, Oishei Children's Hospital, Millard Fillmore Suburban Hospital, and DeGraff Memorial Hospital), Erie County Medical Center, Great Lakes Health System of Western New York, Veterans Affairs Western New York Healthcare System, Catholic Health System (Sisters of Charity Hospital, Kenmore Mercy Hospital, Mercy Hospital of Buffalo, and Sisters of Charity Hospital St. Joseph Campus), and Roswell Park Comprehensive Cancer Center.

Research centers associated with the Jacobs School of Medicine and Biomedical Sciences (and not previously described) include:

- Alzheimer's Disease Translational Genomics Research Laboratory conducts research focused on characterizing the contribution of copy number variations to the genetic architecture of Alzheimer's disease to develop genetic biomarkers for risk stratification; explores olfactory identification deficit as a biomarker of the disease; and uses stem cell technology to study the disease mechanism.
- Buffalo Neuroimaging Analysis Center (BNAC) works to extend the boundaries of knowledge about neurological diseases and disorders through innovative neuroimaging research techniques and the application of bioinformatics resources. The center is equipped with the necessary technology, software and experience to carry out specialized neuroimaging studies, and houses a computer center that performs quantitative analysis of MRI scans. Since its inception in 2000, BNAC has established itself as a world leader in performing neuroanalysis measurements.
- Center for Biomedical Imaging (CBI) provides infrastructure and advanced imaging expertise that is completely dedicated to performing research imaging. It is located on the 7th floor of the Clinical and Translational Research Center (CTRC). The imaging facility is adjacent to the laboratory animal facility and

the preclinical departments and basic research laboratories of the CTRC, which also houses the Clinical Research Center (CRC) on the 6th floor, which has a dedicated suite for clinical research. The CBI has approximately 7,500 square feet of available space. The CBI currently hosts three research imaging scanners: General Electric Discovery PET/CT 690, 3 Tesla Canon Vantage Titan MRI and the 9.4T Bruker Biospin BioSpec 94/20 USR preclinical MRI and cell radiotracer laboratory.

- Center for Developmental Biology of the Lung is a state-of-the-art translational and basic research facility with extensive equipment and technical staff support with a focus on pulmonary development and lung injury and repair. It conducts translational research to prevent and treat disorders of pulmonary transition such as birth asphyxia, persistent pulmonary hypertension of the newborn (PPHN), transient tachypnea of the newborn (TTN) and respiratory distress syndrome (RDS).
- Center for Functional Assessment Research seeks to establish, maintain and disseminate uniformity of instruments that document levels of disability and outcomes of medical rehabilitation for persons with disability and/or chronic health conditions, using state-of-the-art technologies. The center maintains the world's largest database for medical rehabilitation outcomes.
- Center for Research in Cardiovascular Medicine strives to develop novel approaches to improve heart function and to study the efficacy of therapeutic intervention in preclinical models that reproduce human ischemic heart disease and heart failure. Data from these investigators help advance therapies to early-phase clinical trials. Molecular imaging and high-throughput molecular biology is used to understand molecular pathophysiology. Clinical investigations are conducted to evaluate therapies for patients with heart failure, ischemia and arrhythmia.
- Center for Single Molecule Biophysics is an interdisciplinary and interdepartmental group dedicated to studying the structure and function of proteins, nucleic acids and lipids at the single-molecule level.
- Children's Guild Foundation Autism Spectrum Disorder Center is the only center for medically-based, multidisciplinary evaluation and diagnosis of children with autism spectrum disorders in Western New York. Since its establishment in 2010, it takes a team-based approach to child evaluation to determine the diagnosis and/or need for additional testing or services.
- Comprehensive Epilepsy Program conducts clinical research and drug trials focusing on individuals with difficult-to-control seizures and aim to improve treatment, prevention or diagnosis of seizures and epilepsy.
- Cystic Fibrosis Center of Western New York is one of the first centers of its kind in the U.S. Composed of multidisciplinary medical professionals. The center strives to provide exemplary family-centered patient care to patients, to participate in research for improvement of care and treatment, and to educate patients, families, the medical community, and the public about the disease CF.
- Diabetes Center plays a key role in the Western New York community where over 900 children with Type 1 and Type 2 diabetes receive their care. Due in large part to the childhood obesity epidemic, Type 2 diabetes in now being diagnosed in children, with the center as the only pediatric hospital to have received designation of Diabetes Center of Excellence for Type 2 diabetes from the New York State Department of Health.
- Diabetes-Endocrinology Center of Western New York helps patients improve the quality of their lives and health through proper management of and education about their particular diabetes states. Center clinicians specialize in the diagnosis, management and treatment of Type I and Type II diabetes and its complications. The center treats other endocrine disorders such as thyroid disease and metabolic disorders.
- Digestive Diseases and Nutrition Center is a premier center in the U.S. treating children with gastrointestinal and nutritional disorders and disease. Their goal is to prevent, diagnose and treat gastrointestinal, nutritional, hepatic and pancreatic disease in children from birth through young adulthood.
- Hunter James Kelly Research Institute conducts basic research based on a multi-disciplinary approach to understand how myelin is formed, how it is damaged in disease and how it may be repaired. An important focus for the Institute is to understand, prevent and reverse axonal degeneration. The Institute uses a variety of state-of-the-art approaches that include genetic models, bioinformatics, primary cultures of neuronal and glial cells form patients and animal models, neurophysiology and live imaging.

- IRA G. Ross Eye Institute Research Center is dedicated to preserving and protecting vision. Physicians with both medical and surgical management of routine and complex eye disorders use state-of-the-art technology for diagnosis, treatment and repair. The center performs painstaking research to unlock barriers to discover cures.
- Jacobs Multiple Sclerosis Center for Treatment and Research is a clinical partner of the Department of Neurology. The center conducts research to understand mechanisms of disease progression, with a primary focus on the role of environmental factors and environmental-gene interactions. It also conducts clinical trials for new pharmacologic interventions.
- Liver Biorepository at the UB Clinical and Translational Research Center collects, stores and manages clinically annotated human liver samples for use in clinical and translational research. The center offers samples from patients with a full spectrum of liver conditions, including fatty liver disease and hepatitis B and C.
- National Center for Physician Training in Addiction Medicine focuses on developing curricula and training primary care providers to specialize in the prevention and treatment of substance use disorders.
- NeuroMolecular Imaging Center investigates disease pathophysiology in humans and animal models of human disease using multimodality imaging. The center uses functional modalities, including positron emission tomography, single-photon emission computed tomography, fMRI and structural modalities including MRI and computerized tomography.
- Neuromuscular Disease Research Center conducts clinical research and clinical trials in a wide variety of neuromuscular disorders with a focus on myasthenia gravis and peripheral neuropathy, including neuropathic pain.
- Neuropsychology Center employs behavioral psychometrics to understand how cerebral disease affects personality, cognition and psychiatric stability. The center develops widely adopted tests, notably memory tests, to determine areas of cognitive impairment in multiple sclerosis, cerebral injury and disease, and other conditions.
- Patient Safety Research Center works to reduce the national burden of medical errors through educational and research programs using collaborative, multidisciplinary team-based safety measurement and enhancement.
- Pediatric Multiple Sclerosis Center at John R. Oishei Children's Hospital conducts pediatric multiple sclerosis research. It is a designated center of excellence affiliated with the National MS Society.
- Primary Care Research Institute is a transdisciplinary research unit based in the Department of Family Medicine. The Institute pursues a dynamic agenda of clinical and health services research designated to benefit patients, inform policy and enhance health systems. Evidence-based strategies are applied to diverse problems that affect large populations across the lifespan, ranging from chronic disease and addiction to health disparities and healthcare workforce shortages. The group's focus includes areas such as community based participatory research, health disparity research, management of complex chronic conditions, health care practice transformation, comparative effectiveness research, translation of evidence into practice, and health workforce training.
- Robert Guthrie Biochemical & Molecular Genetics Laboratory performs over 5,000 specialized diagnostic tests annually for inborn errors of metabolism with a particular emphasis on the metabolic myopathies and mitochondrial disease. Its main goal is to provide comprehensive diagnostic testing that will facilitate the arrival at a final diagnosis for the patient through coordination with clinical, histochemical and molecular findings.
- Canon Stroke and Vascular Research Center focuses on research related to the diagnosis and treatment of vascular disease through minimally invasive image-guided interventions, improved imaging modalities and devices, and better understanding of hemodynamics. The overall goal is to have innovations emerging from the center quickly translated into clinical practice and implemented by industry so that they may directly benefit patients.

- UB Center for Successful Aging, housed in the Division of Geriatrics and Palliative Medicine in the Department of Medicine, is focused on advancing interdisciplinary research and interprofessional practice for older adults.
- Witebsky Center for Microbial Pathogenesis and Immunology is comprised of research scientists and their students/fellows who share a common interest in understanding the molecular mechanisms of infectious diseases and host defenses against them. Its application of genetic, biochemical and immunological concepts and technologies meld the diverse research foci into a single interactive unit.

School of Public Health and Health Professions

UB's School of Public Health and Health Professions is one of only a handful of schools across the country that includes health-related professions as an integral component of the public health educational and research system. The philosophy of the school is to improve the health of populations, communities, and individuals. The School of Public Health is composed of five departments, each with its own discipline-specific research facilities as well as access to shared resources.

- Biostatistics is home to faculty, staff, students, and post-doctoral fellows. The department is dedicated to advancing knowledge in the field substantively and methodologically. They conduct important methodological, theoretical, and applied research, as well as serve as vital contributors to collaborative research with UB and community partners.
- Community Health and Health Behavior is comprised of faculty who are renowned researchers and produce innovative solutions to improving health for individuals, communities, and populations here in Western New York and across the globe. Its graduates are prepared to conduct research on behavioral and community factors influencing disease prevention and health promotion; develop, implement, monitor, and evaluate public health programs addressing behavioral and community health; and create positive changes in the health of their local, regional and broader communities.
- Epidemiology and Environmental Health focus on understanding the determinants and prevention of disease, on the role of environmental factors in health and disease and how the administration of health programs can help implement this understanding. The department is dedicated to research, training, and service; bringing faculty, students and postdoctoral fellows with widely diverse backgrounds to engage in developing new ideas, methods and knowledge to improve the health of populations; and continuing educating leaders who play key roles in the public health arena.
- Exercise and Nutrition Sciences offers a broad understanding of the human body, including physiological, biomechanical and nutritional factors. Its vision is to improve the public's health and well-being through our scientific discoveries, our education of researchers and professionals, and our commitment to outreach and community education. The department's research will allow it to better understand how exercise and nutrition influence health, disease prevention and individual function performance.
- Rehabilitation Services encompasses several disciplines, including occupational therapy and physical therapy, devoted to the quality of life for people whose functional capabilities are limited. The department is dedicated to advancing knowledge through research in the disciplines of occupational therapy and physical therapy, developing students and practitioners, and developing meaningful interdisciplinary collaborations in education, research and practice that promote and improve the health of people across the region, country and world.

Research centers associated with the School of Public Health and Health Professions (and not previously described) include:

- Aging and Technology Research Center is dedicated to promoting health and independent living among older adults and their caregivers. The center performs research on technological solutions to problems associated with aging.
- Center for Research and Education in Special Environments (CRESE) is a center of excellence for applied physiology. The CRESE facility can simulate any environment, from the extremes of the deep ocean to desert, arctic and rainforest climates to high altitude and space. It also houses a unique altitude and wet hyperbaric chamber bracketing 100,000 feet of altitude and 5,600 feet of depth. CRESE also has the world's only annular (endless) pool and operates one of the world's few human-rated centrifuges.

- Center for Knowledge Translation for Technology Transfer (KT4TT) is a program of the Center for Assistive Technology sponsored by NIDILRR. The Center assists NIDILRR Agency grantees and applicants who plan to conduct or who are conducting technology-oriented R&D projects to achieve stakeholders' increased understanding of technology transfer processes and practices that lead to successful communication; to increase grantee's capacity to plan and engage in technology transfer activities; and to increase grantee's rate of success in the transfer of rehabilitation technology projects to the marketplace, into standards/guidelines or other intended applications.
- Center for Assistive Technology (CAT) explores the functional utility of Assistive Technology devices and services in support of persons with disabilities. CAT develops and synthesizes knowledge about assistive devices to aid people with functional impairments. Activities integrate multiple disciplines and span economic sectors to improve the quality of life for persons with any level of impairment, across all ages and within any environment.
- Center for Assistive Technology (CAT) Client Services provides awareness of the use of Assistive Technology (AT) helping people of all ages with various disabilities, illnesses and functional impairments apply AT for daily living, school, work, recreational and leisure activities. Services can help people live more independent lives and also facilitate improved health, wellness and disease prevention.
- Population Health Observatory (PHO) is a public health research, training and informatics center founded in 2003. The PHO applies biostatistical and computational expertise to analyze large population based data sets, mining information from them to enhance knowledge and practice of public health. PHO's goal is to provide policy makers, program managers, public health professionals and regulatory agencies with information that promotes data driven health policy and decision making, evidence based program management, scientifically sound program evaluation and accurate information for regulatory decisions.
- WHO Collaboration Center on Health and Housing is a collaboration of the School of Public Health and School of Architecture and Planning. Its focus is on research and technical assistance in the design of the built environment that will foster the health and functioning of all people, including those with disabilities.
- Women's Health Initiative (WHI), sponsored by the NHLBI, is a long-term national health study that focuses on strategies for preventing heart disease, breast and colorectal cancer, and osteoporosis in postmenopausal women. The original Women's Health Initiative study has received extension (and ancillary) studies, most currently collecting annual health information from consenting WHI participants through 2020, focusing on cardiovascular events and aging.

School of Dental Medicine

UB's School of Dental Medicine plays a critical role in advancing oral health in the Buffalo-Niagara region and around the world. Established in 1892, the School of Dental Medicine continues to educate general practitioners, specialists and biomedical scientists in the art and science of oral health through our comprehensive accredited programs. A wide range of interdisciplinary training, informational and support options are available to students among the various facilities and resources throughout the campus and surrounding area. The school is made up of the following seven departments:

- Oral Biology was the first of its program in an American dental school. It is a highly dynamic and supportive research and training environment for undergraduates, graduate students and clinical fellows involved in cutting edge research into the molecular basis of diseases that affect a staggering number of people in the U.S. and abroad. The department's focus is on the creation, dissemination, and application of knowledge in oral and craniofacial health science. It supports basic and clinical research directed to solve important problems affecting oral and general health.
- Oral Diagnostic Sciences mission is to teach, conduct research and provide service in the differential diagnosis and treatment of orofacial diseases and disorders. Emphasis is given to the use and integration of biological, behavioral and clinical sciences that are relevant to the different diagnosis of pathological conditions in the orofacial region, and to the utilization of critical thinking skills in that process.
- Oral and Maxillofacial Surgery provides didactic and clinical training for dental students, surgery residents and graduate students. Emphasis is put on the basics of patient assessment and diagnosis and proficiency in routine dentoalveolar surgery.

- Orthodontics provide children, adults and seniors with straighter teeth and healthier smiles through its training of dental students and offering of clinical care.
- Pediatric and Community Dentistry provides predoctoral and postdoctoral specialty training and clinical experience in the diagnosis and treatment of the developing definition of children, adolescents and young adults. Emphasis is placed on specialty training for patients with medical, mental, physical and developmental disabilities to ensure that vulnerable populations are provided with care by the future generations of dental professionals. Overcoming cultural barriers is a key aspect of achieving optimal patient care.
- Periodontics and Endodontics has played a pivotal role in training world-class clinicians, researchers and academicians who have now become leaders in dental education and research. The comprehensive mission is to prepare students in the art of periodontology, implantology and endodontics to meet and exceed the standards necessary for accreditation; educate dentists to become specialists in the field for academic, research and clinical careers; advance knowledge through research and community service; and educate and facilitate the continuing education of dental professionals in practice.
- Restorative Dentistry is the largest and most comprehensive unit in the school, and includes the Division of Operative Dentistry and Division of Prosthodontics. The department is committed to continuing the improvement of well-being and oral health in the community by providing a stimulating environment to educate students, dentists and other professionals; providing direct comprehensive restorative clinical services; conducting oral health research and other scholarly activity; and developing future leaders of the profession in education, research and organized dentistry. It also helps ensure the next generation of dentists will excel in their professions to be life-long learners.

Research centers associated with the School of Dental Medicine (and not previously described) include:

- Center for Dental Studies has a long history of working with industry. One of the center's strengths is its ability to provide comprehensive services, including developing research protocols, performing basic scientific and clinical studies for new project introduction and/or project enhancement, coordinating multicenter research, and facilitating technology transfer to industry.
- Center for Orofacial Pain Research focuses on research questions that revolve around pain, function, diagnosis and classification. The research activities take place within three laboratories for primary data collection: neurosensory, biomechanics and psychophysiology.
- The Center for Translational and Clinical Biophotonics focuses its interests in soft tissue laser surgery, hard tissue (dental) interactions, endodontic interactions and therapy, and laser implications in cancer promotion, detection and photodynamic therapy treatments.
- Industry/University Center for Biosurfaces (IUCB) focuses on understanding, predicting and control of biological adhesion. Through such understanding, IUCB seeks to predict how living cells and biological matter will attach to other materials to safely, effectively and economically control the speed and strength of biological surface interactions for the benefit of personal, public and environmental health. Multidisciplinary studies of the mechanistic details of "conditioning" film formation, biopolymer deposition, and cell and protein adhesion to synthetic materials and model tissues are in progress.
- Periodontal Research Center has been supported by the NIH since 1977 as one of their specialized clinical research centers for the study of periodontal disease. The center focuses its current activities on longitudinal studies directed at modulating risk factors within populations at risk for periodontal disease.

School of Nursing

For over 75 years the UB School of Nursing (SON) has provided high quality nursing education. The SON offers three Bachelor of Science (BS) degree programs; a Doctor of Nursing Practice (DNP) in four programs (Adult Gerontology Nurse Practitioner, Family Nurse Practitioner, Nurse Anesthetist and Psychiatric/Mental Health Nurse Practitioner); a post-master's DNP in seven programs (Adult-Gerontology Clinical Nurse Specialist, Adult-Gerontology Nurse Practitioner, Child Health Nurse Practitioner, Family Nurse Practitioner, Nurse Anesthesia, Psychiatric/Mental Health Nurse Practitioner and Women's Health Nurse Practitioner); a Master's Degree in Nursing Leadership in Health Care Systems; and a Doctor of Philosophy (PhD) degree.

The Center for Nursing Research (CNR) is dedicated to providing resources to support faculty and students to develop and advance nursing and interprofessional science. Center staff provide methodological and clinical research consultation to the School of Nursing faculty, students and staff. The CNR is dedicated to the following goals:

- Expedite preparation of high-quality grant proposals
- Foster energy and interest in research
- Support the creation of quality manuscripts and presentations on nursing research
- Stimulate the development of a community of scholars/researchers
- Increase the knowledge base of nursing
- Establish a repository of research resources
- Enhance research skills and productivity through multidisciplinary teams

The Center is a repository for information on internal and external sources of funding, including guidelines and application forms. The Center also houses a research library and research instrument repository.

School of Pharmacy and Pharmaceutical Sciences

The UB School of Pharmacy and Pharmaceutical Sciences is ranked among the top pharmacy schools in the United States. The School of Pharmacy and Pharmaceutical Sciences' building has 160,000-square foot facility includes many green-design features, such as maximizing natural daylight (75% of all space in the building receives natural light), creation of social spaces and the reuse of the Acheson Hall building footprint. The building offers a state-of-the-art Pharmaceutical Care and Teaching Center and has improved linkages between all of UB's health science schools. The school is home to over 20 research facilities. The Drug Development service brings together the expertise of Roswell Park Comprehensive Cancer Center and the School of Pharmacy and Pharmaceutical Sciences to provide a resource (including training) in preclinical and early clinical development of novel compounds for investigators. The Drug Development service provides a centralized resource for preclinical pharmacology, pharmacokinetic-pharmacodynamics and early phase clinical trial design, conduct and management.

UB’s School of Pharmacy and Pharmaceutical Sciences has robust research centers in both the department of pharmacy practice (eight centers) and the department of pharmaceutical sciences (three centers). Major federal and external programmatic funding sustain the valuable work conducted in these areas.

- Pharmaceutical Sciences offers a collaborative research environment to conduct advanced research alongside its 16 internationally renowned faculty. As students graduate to scientists, they possess a competitive advantage to pursue successful careers in academia, regulatory agencies and the pharmaceutical and biotechnology industries.
- Pharmacy Practice prepares integration of all aspects of healthcare, acknowledging unique challenges and opportunities, to provide highly respected healthcare professionals that instruct patients and other healthcare colleagues on a variety of medication therapy management issues. The department’s faculty engage in active clinical and research scholarship with expertise in specialties that include ID/HIV, pediatrics, geriatrics, nephrology, oncology, neuropharmacology, cardiac care, ambulatory care, palliative care, pharmacoeconomics and healthcare disparities.

Research Centers based in the School of Pharmacy and Pharmaceutical Sciences

The Pharmaceutical Genetics Laboratory provides research support for an array of basic molecular biology techniques to assist students and faculty in addressing questions in pharmacogenetics research. The laboratory has the necessary equipment to perform quantitative real-time PCR, DNA genotyping, DNA cloning, recombinant protein expression, fluorescence microscopy and imaging. The facility provides varied equipment including real-time PCR cyclers (Bio-Rad and Stratagene), a Bio-Rad photo documentation system, nano drop spectrophotometers, a Zeiss Axiovert 200M microscope, gradient PCR thermal cyclers, refrigerated centrifuges and ultracentrifuges, dedicated -20 ºC and -80 ºC freezers and miscellaneous equipment.

Collaborative Computational Facilities Computation and visualization play a key role in our educational and research activities. We offer courses that provide a heavy concentration in quantitative disciplines, including physical pharmaceutical sciences, pharmacokinetics, pharmacodynamics, pharmacogenetics and pharmacogenomics. Specialized software holdings not only support research and education in PK/PD/PG, but also in molecular computation and visualization.

Basic skills training is offered in computation related to the practice of pharmacy. In terms of research, both undergraduate and graduate students receive hands-on research training by participating in externally funded research projects. Analysis of data and presentation of research findings are a mainstay of research training.

Research centers associated with the School of Pharmacy and Pharmaceutical Sciences (and not previously described) include:

Center for Drug Delivery is a dynamic academic home for investigators interested in discovering and advancing innovative drug delivery and therapy strategies. It seeks to actively pursue industry partnerships allowing UB biotechnologies to translate into economic growth opportunities and revenue generation; to foster interdisciplinary training environments educating the next generation of translational scientists interested in drug delivery and therapy development; and to create delivery technologies for investigator projects and formulate translational services supporting further drug development.

Center for Protein Therapeutics works with leading pharmaceutical companies to advance the development of next generation protein drugs, providing improved effectiveness and convenience for users. The Center conducts leading-edge research and provides structural training programs in concert with other centers at the New York State Center of Excellence in Bioinformatics and Life Sciences.

The Center of Excellence in Pharmacokinetics and Pharmacodynamics was established to promote the development and application of PK/PD to the problems and challenges of drug therapy. The Center's primary areas of research include translational pharmacology, mechanism-based PK/PD modeling, modeling of disease and disease progression, PK/PD systems, PD interaction and PK/PD structure-activity.

Center for HOPE (Health Outcomes, Pharmacoinformatics and Epidemiology) is the foremost producer and evaluator of the healthcare evidence base, serving local, regional, national, and international partners of UB as well as healthcare providers across the globe. The focus of its effort is on optimization of pharmacotherapy in underserved populations.

Center for Integrated Global Biomedical Sciences is an international hub for innovation that brings together scientific disciplines in a nontraditional approach to build capacity to address regional as well as global challenges. The center uses education, training and research to promote novel discovery, maximize technology and foster translation.

Global Health Initiative offers multiple initiatives which exposes students to practical global health concerns, promotes culturally competent healthcare and fosters the development of servant leadership in global populations locally, nationally and internationally.

Laboratory for Antimicrobial Pharmacodynamics is focused on novel approaches to combat bacterial resistance by studying interdisciplinary areas including antimicrobial pharmacokinetics and pharmacodynamics, clinical pharmacology, bacterial genetics and translational medicine. The laboratory utilizes a variety of approaches to optimize the profile of new and existing antibiotics including susceptibility and bactericidal testing, the cutting edge hollow fiber infection model and advanced pharmacometric analyses.

Research Pharmacy is a New York State-licensed outpatient facility focused on providing UB researchers pharmaceutical support during all aspects of their research. Through its highly skilled pharmacy team, the Research Pharmacy provides support in a variety of areas including federal and state legislation, customization of dosing regimens, management of medication dispensation and blinding and specialized compounding.

Translational Pharmacology Research Core (TPRC) is a collaboration between other research cores in the Center of Excellence in Bioinformatics and Life Sciences, School of Pharmacy and Pharmaceutical Sciences, the Clinical and Translational Science Institute and other units within the University at Buffalo and the Buffalo Niagara Medical Campus. The TPRC has grown and collaborates across decanal units with UB as well as throughout the New York State.

Transplantation Immunosuppressive Pharmacology Research Program focuses on understanding the relationship between the pharmacokinetics of immunosuppressive drugs, pharmacodynamics of immunologic markers, and pharmacogenomic endpoints as related to gender, race, and age of renal transplant recipients.

UB-UZ Research Training Program (HRTP) is supported by the NIH Fogarty International Center and is a postgraduate fellowship training initiative with emphasis on HIV/AIDS clinical pharmacology between UB and the University of Zimbabwe (UZ). Program faculty at both institutions contribute mentored training to UZ students

and scholars who will contribute clinical pharmacology expertise to multidisciplinary teams to achieve the HIV/AIDS research goals for Zimbabwe.

School of Architecture and Planning

This is the only school of architecture and planning within the 64-campus State University of New York (SUNY) system. As a community of thought leaders and aspiring architects and urban planners, thoughts and actions are on the edge of knowledge and practice, guided by a culture of experimentation, a core belief in learning by doing, and a spirit of public service and inclusion. The school proves each and every day that design and planning are agents of change for community, place, culture, social justice and the natural world.

Research centers associated with the School of Architecture and Planning (and not previously described) include:

- Center for Architecture and Situated Technologies (CAST) focuses on the evolving and growing implications of new technologies within the built environment: social, political, ecological and material.
- Center for Inclusive Design and Environmental Access (IDeA Center) focuses on research, development, education, dissemination, and design projects related to universal design.
- Food Systems Planning and Healthy Communities Lab is dedicated to studying the role of planning and policy in facilitating sustainable food systems and healthy communities.
- UB Regional Institute / Urban Design Project is a major research enterprise for the School of Architecture and Planning.

College of Arts and Sciences

With 27 departments, 16 academic programs, and 23 centers and institutes, the College of Arts and Sciences offers students the resources of a major research institution – such as cutting-edge facilities and faculty at the forefront of their fields – combined with the support of a small university setting and a commitment to community engagement through research, study abroad, internships and service programs.

Graduate School of Education

A professional school with a social mission to create and apply knowledge informed by research on human development, educational policy, teaching and information science, the Graduate School of Education offers nine doctoral programs, 48 master's programs and 18 advanced certificate programs, many of which are on-line. Faculty and students are involved in dynamic, collaborative and transformative research that impacts local, national and global communities.

School of Engineering and Applied Sciences

Eleven undergraduate degree programs, 18 master's programs and 10 doctoral degree programs are offered through the School of Engineering and Applied Sciences. Multidisciplinary teams collaborate with the school's research centers, institutes and programs to address such topics as healthcare, personal security and recovery from natural disasters. The Department of Biomedical Engineering spans both the School of Engineering and the Jacobs School of Medicine.

School of Social Work

The diverse community of the school is unified by its vision of a better society achieved through the generation and transmission of knowledge, promotion of social justice and service to humanity. Faculty research addresses many critical topics, including substance abuse, trauma, aging, health access, mental health, chronic disease, child welfare, sexuality and cross-cultural practice.

Research centers associated with the School of Social Work (and not previously described) include:

- Buffalo Center for Social Research facilitates social work faculty and graduate students' research programs by providing assistance in securing extramural support for their scholarly, research, teaching and community service activities through individual, collaborative and interdisciplinary grant proposal submissions.
- Immigrant and Refugee Research Institute create and shares knowledge on immigrants and refugees to improve their lives with a focus on Western New York newcomers.

School of Law

- The UB School of Law is the only law school in the State University of New York system and is one of only a few law schools located on an international border. The School of Law offers a myriad of cross-border learning opportunities, including a new cross-border legal studies concentration. Many nationally prominent faculty members have a Ph.D. in addition to their law degrees, which allowing the school to offer a wide range of interdisciplinary course options taught by experts. A unique feature of the UB School of Law is a collaborative initiative with the legal community. Students, faculty, staff, loyal employers, judges. and a wide-ranging network of alumni are all deeply engaged with the law school community. They are mutually supportive of one another and directly involved and committed to the educational process.

School of Management

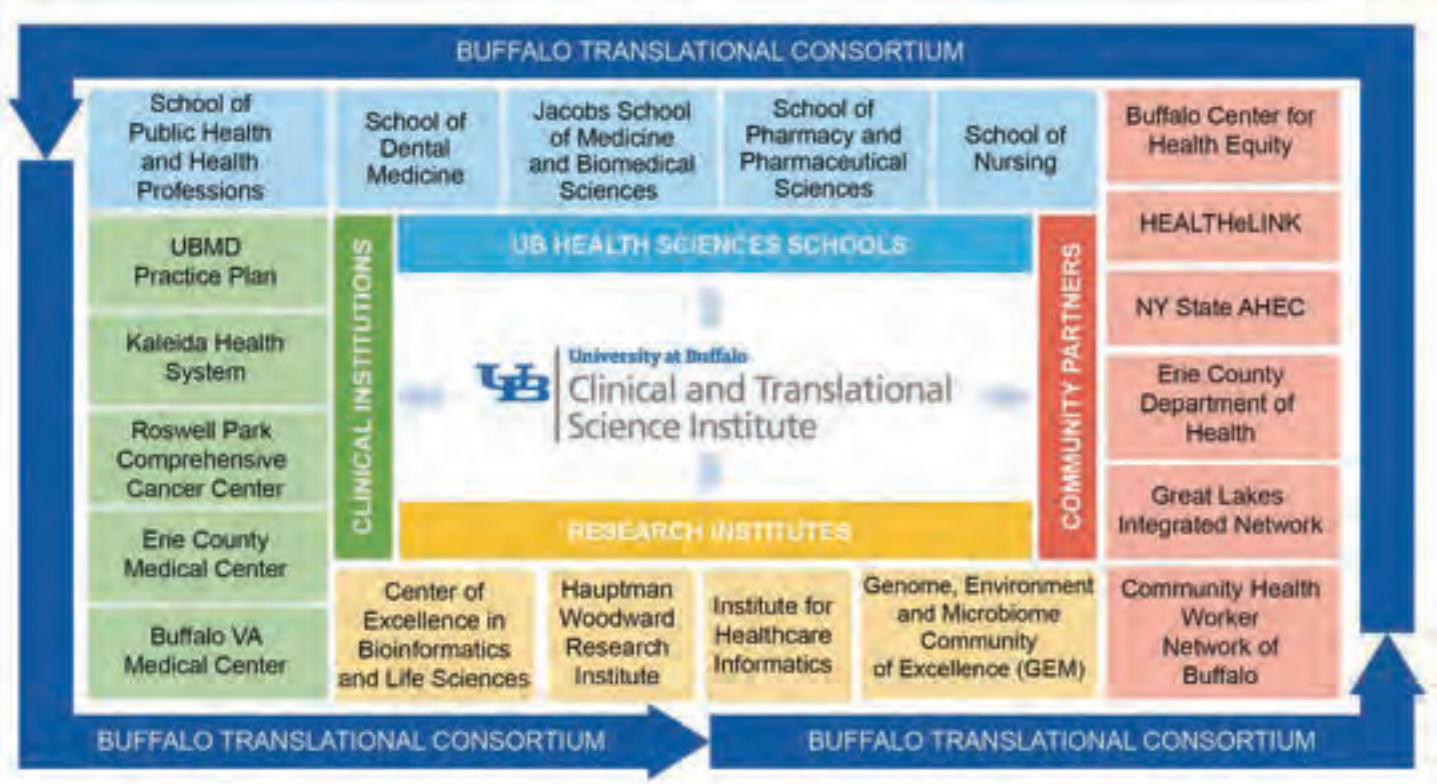
- The UB School of Management has been recognized by *The Wall Street Journal* as one of the best in the world for seven consecutive years. The mission of the school is to discover and deepen our understanding of management concepts and applications that drive effective organizations and use them to produce principled and insightful leaders who create positive change in the world. The School of Management engages in a wide variety of public service activities that benefit the Western New York region and beyond.

UB Health Sciences Library

- The mission of the UB Health Sciences Library is to advance knowledge by developing, managing and providing access to health information resources. Located on the UB South Campus, the Health Sciences Library focuses its resources and services to meet the information needs of the University's five health sciences schools as well as health professionals and organizations throughout Western New York.
- Resources include over 10,000 current biomedical journal subscriptions in all formats, over 365,000 volumes of book and journal titles in multiple formats, a strong collection of audiovisual programs and a well-used history of medicine collection highlighting books and rare medical instruments. A growing array of electronic information resources including MEDLINE, CINAHL, EMBASE, PsycINFO, Web of Science, Evidence Based Medicine Reviews and Nursing Reference Center are available to all faculty, staff and students either on campus or remotely. Visitors to the library may access library resources on site. Instruction on aforementioned and other curriculum and resource-based tools are available in person or online.
- Reference assistance is provided in person, by phone, chat or via email, AskHSL@buffalo.edu. Librarians are available to share searching expertise and provide information research consultation for faculty and students working on a thesis, dissertation and research project or grant proposal. In addition, interlibrary loan and document delivery service either electronically or in print are provided via Delivery+.

Buffalo Translational Consortium

The UB Clinical and Translational Science Institute leads the Buffalo Translational Consortium, which is comprised of the five UB health sciences schools, leading clinical institutions (Roswell Park Comprehensive Cancer Center, Kaleida Health System, Erie County Medical Center, UBMD Practice Plan and Buffalo Veterans Administration Medical Center), research institutes and community partners. All partners share a commitment to perform research with a vision to improve methods of prevention and treatment and to test and implement innovative approaches to improve health and reduce health disparities in our community. (see figure below)



UB Health Sciences Schools

- Jacobs School of Medicine and Biomedical Sciences (described previously in this document)
- School of Dental Medicine (described previously in this document)
- School of Nursing (described previously in this document)
- School of Pharmacy and Pharmaceutical Sciences (described previously in this document)
- School of Public Health and Health Professions (described previously in this document)

Clinical Institutions

- Buffalo Veterans Administration Medical Center is one of two members of the VA Western New York Healthcare System. The Buffalo VA has provided medical, surgical, mental health and long term care services through a range of inpatient and outpatient programs since 1950. VA Western New York Healthcare System is academically affiliated with UB along with 66 additional universities and professional schools. Its researchers have earned worldwide acclaim in developing the cardiac pacemaker, as well as other recent breakthroughs.
- Erie County Medical Center (ECMC) is one of the area's leading healthcare providers and one of the country's most modern, functional and efficient healthcare delivery systems. ECMC is the regional center for trauma, burn care, behavioral health, transplantation, and medical rehabilitation, and a number of Centers of Excellence. It is also a major teaching facility for UB, making it a top destination for research and innovation. ECMC provides care to the eight counties of Western New York and Southern Ontario, Canada.
- Kaleida Health System is the largest healthcare provider in Western New York, with 40 percent of the market share, serving the area's eight counties with state-of-the-art technology and comprehensive healthcare services via five hospitals, two long-term care facilities, over 80 outpatient clinics, including school-based health centers, and home healthcare. In addition, Kaleida Health's hospitals support UB residency programs, training more than 700 residents each year. Kaleida Health Laboratories in the Great Lakes Health System are the dominant NYS/CLIA-certified clinical laboratories in Western New York.
- Roswell Park Comprehensive Cancer Center, America's first cancer center since 1898, is a freestanding comprehensive cancer center that brings together the best medical and scientific minds in cancer care who are dedicated to the mission to understand, prevent and cure cancer. Roswell Park practices a patient-centered, multidisciplinary approach where a team of cancer experts, including surgical, medical and

radiation oncologists alongside oncology nurses, participate in every patient's care in one location. With more than a century of groundbreaking research, Roswell Park commits the infrastructure, intellectual capital and necessary resources to convert scientific discoveries into real-world products and applications. Roswell Park actively seeks to help medically underserved and high-risk populations through a variety of programs.

- UBMD Physicians Group is the single largest physicians group in Western New York, with more than 500 doctors in 18 medical specialties, offering a full range of primary and specialty care for children, adults and seniors. In addition to practicing medicine, UBMD doctors teach medical students and residents at the Jacobs School of Medicine and Biomedical Sciences and conduct clinical trials.
- Great Lakes Integrated Network (GLIN) is a capital partner of Kaleida and includes ~500 providers in community practices (half primary care) and 175,000 lives, primarily in Erie County, including urban and rural practices. GLIN has a data warehouse using HealtheIntent and will share data with our IHI data repository, enabling identification of clinical trial cohorts. The GLIN collaboration creates a valuable opportunity to bring clinical trials to community-based practices.

Research Institutes

- Hauptman-Woodward Medical Research Institute is committed to finding fundamental causes of many diseases. Its scientists use a methodology known as structural biology, allowing them to create 3D models of molecules that build up cells. Results of their investigations provide insight to how molecular machines work. The institute also seeks to make technological improvements in the process of creating these 3D molecular models to enhance productivity of scientists all over the world.
- Institute for Healthcare Informatics (IHI) (described previously in this document)
- New York State Center of Excellence in Bioinformatics and Life Sciences is a hub for life sciences innovation and technology-based economic development driving scientific discovery, facilitating collaboration among academia, industry and the public sector to create jobs that directly impact the region's and state's economics. The Center of Excellence in Bioinformatics and Life Sciences is home to over 250 scientists and research staff with biological, physical and computational expertise, all engaged in interdisciplinary biomedical research with collaborators from across the region, country and globe.

Community Partners

- Buffalo Center for Health Equity The mission of the Buffalo Center for Health Equity is to eliminate race, economic and geographic-based health inequities in Western New York by changing the social and economic conditions that cause illness and shorten lives among the sickest of the region. The Center uses policy analysis, research, assessment, and evaluation, advocacy, community engagement and education, and program development and implementation to eliminate these inequities. The Center works collaboratively with community members and organizations as well as the public and faith-based sectors to advance this multi-level agenda. The work is focused on the social and economic determinants of health (failing schools, high unemployment, low property values, poor access to public transportation, absence of grocery stores, lead contamination in homes, highway pollution, brownfields, and poor access to healthcare) primarily in the 14204, 14206, 14211, 14212, 14215 zip codes where African Americans are dying at three times the rate as their white counterparts. Buffalo Center for Health Equity is a community-based 501(c)3 center that includes active involvement of multiple sectors of the community, including the faith-based community, healthcare providers, labor, health insurance, non-profits, the criminal justice system and elected officials.
- HEALTHeLINK is a collaboration of physician, hospital and insurance organizations to share clinical information in efficient and meaningful ways to improve delivery of care, enhance clinical outcomes and control healthcare costs throughout the Western New York region. HEALTHeLINK is working towards the vision of creating community-based virtual medical records and other clinical applications. This ultimately leads to broader, quicker access to medical information to be translated into better clinical outcomes, increased professional collaboration, improved efficiency and lower costs, and overall improved patient safety.
- New York State AHEC System is a statewide, community-based health workforce development initiative with a mission to enhance access to quality healthcare and improve healthcare outcomes by addressing the

health workforce needs of medically disadvantaged communities and populations via community academic partnerships.

- Community Health Worker (CHW) Network of Buffalo was formed in 2010 through the efforts of a group of advocates in health care, public health, academia, and community-based organizations looking to foster "bottom up" strategies to improve community health in Buffalo and beyond. The CHWNB developed as frontline workers of and from the communities they serve (Community Health Workers) and stakeholders came together in the areas of health care, public health, housing, education, environment, food access, and social services; with the intent to empower community members to define their own challenges and opportunities and take action to self-determine their future. The CHWNB's mission is to provide education, networking, and support to ensure all people and communities have the resources and power they need to realize their full potential for health and well-being, with a focus on diversity, inclusion, and equity.

Equipment

As outlined in the proposal, *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers,* we will attract, train and mentor early-career investigators from all 12 UB schools to perform research to achieve health equity in our region by addressing the complete range of social determinants of health (SDOH). Because we will not know the specific projects or mentors until we solicit letters of intent and fund pilot studies proposals, it is difficult to predict pertinent equipment. The mentors of investigators will be accomplished, well-funded faculty, who have well equipped research environments and laboratories (in the case of laboratory-based projects).

The Facilities and Resources section includes a comprehensive summary of the 12 UB schools and many of the most pertinent Core Facilities and Research Centers. UB and Roswell Park Comprehensive Cancer Center have comprehensive, well-equipped core facilities with modern, appropriate equipment for the cores to provide state-of-the-art support to pilot studies awardees.

Jacobs School of Medicine and Biomedical Sciences
University at Buffalo

Office of the Vice President for Health Sciences and Dean

July 26, 2023

Dear officers of NIMHD and review committee members,

In response to and in support of the required materials for the submission, *Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers,* to the National Institute on Minority Health and Health Disparities (NIHMD). I commit on behalf of our research efforts and the university that the University at Buffalo and our partners in this submission agree to maintain our current expenditures for activities not less than the expenditures maintained by the institutions in the fiscal year preceding receipt of this award.

We also agree with respect to any Federal amounts received by the Center or consortium and available for carrying out authorized activities, the institutions involved agree that the institutions will, before expending the award, expend the Federal amounts obtained from sources other than the award.

Sincerely,

Allison Brashear, M.D., M.B.A.
Vice President for Health Sciences
Dean, Jacobs School of Medicine and Biomedical Sciences

955 Main Street, Room 6190, Buffalo, NY 14203-1121
716.829.3355 (F) 716.829.2179 www.medicine.buffalo.edu

Special Eligibility Requirements

The University at Buffalo (UB) Jacobs School of Medicine and Biomedical Sciences, the lead institution for this proposal, is making significant, efforts to recruit and retain members of minority health disparity populations and other health disparity populations enrolled as students. The School of Medicine includes undergraduate college students, graduate students in PhD and masters' degree programs, and medical students in training for MD degrees. We outline here some of the programs and strategies that we have developed and implemented along with data showing the substantial progress reflected in a steadily increasing proportion of students who are underrepresented in medicine and science.

Data reported in this document are provided by the UB Office of Institutional Analysis in the Office of the Provost.

Medical Students

The admissions policy has been critical in achieving the medical school's mission of admitting a diverse class of highly qualified individuals, of the highest integrity and ethical standards, who will become the next generation of competent physicians, medical educators, and clinical investigators.

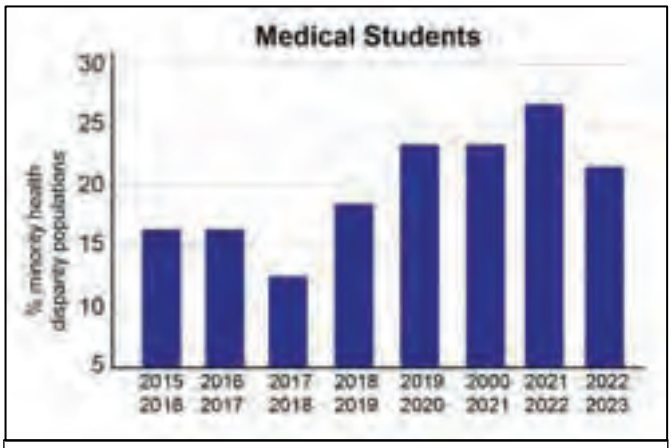


Figure 1. Percent of medical students admitted who are members of minority health disparity populations or other health disparity populations by year.

As part of diversity as a core value, the School of Medicine's goal is to recruit students that bring a wide variety of life experiences, personal interests, and academic achievements. To achieve diversity in medical admissions the school employs a **holistic review process**. Holistic review provides a means to tailor the individualized assessment of an applicant's capabilities through balanced consideration of life experiences, attributes, and academic metrics that when considered in combination, predict how the individual might contribute value as a medical student and physician. Assessment criteria focus on essential and unique attributes that include, but are not limited to, academic and personal achievement, intellectual curiosity, industriousness, obstacles overcome, commitment to service, compassion, personal integrity, communication skills, potential for leadership and unique personal characteristics. Each entering class is selected from the total applicant pool to include individuals whose credentials indicate their dual capacity to meet the rigorous training requirements of medical school and to contribute to the diverse learning environment of their fellow students and ultimately to the diverse practice environment of the population served. **Figure 1** shows the percentage of medical students admitted who are members of NIH-designated minority health disparity populations or other health disparity populations by year.

The Associated Medical Schools of New York (AMSNY) Post Baccalaureate Program, hosted by UB Jacobs School of Medicine and Biomedical Sciences, has had a **substantial regional impact in expanding the pool of physicians from diverse backgrounds.** UB hosts a one-year program to prepare underrepresented, economically, and educationally disadvantaged students for medical training in seven New York State medical schools that conditionally accepted them. Of 607 students (all from underrepresented or economically disadvantaged backgrounds) admitted to the program since 1991, 92% matriculated in medical school and 87% graduated. Funded by the New York State Department of Health, we enroll 20-25 students annually (4-5 per year subsequently enroll at UB). All participants attend tuition-free and receive a living stipend from AMSNY.

Graduate Students in the School of Medicine

The PhD Program in Biomedical Sciences provides an entry portal and a common first-year curriculum, equipping graduate students with core knowledge and concepts to support pursuit of a doctoral degree in one of our several participating disciplines. After the first year, students join one PhD program while still collaborating across research areas. Recruitment activities include attendance at national events focused on increasing graduate school applications from diverse populations, including Society for Advancement of Chicanos and Native Americans in Science (SACNAS) and the Annual Biomedical Research Conference for Minoritized Scientists (ABRCMS). We work across UB STEM decanal units to increase our reach and presence at these events. We have also developed pipelines with key institutions (City University of New York, John Jay College

of Criminal Justice, University of Puerto Rico), and a focus on UB's diverse population of undergraduates (e.g., Collegiate Science and Technology Entry Program and McNair Scholars). UB also recruits diverse scholars via its Initiative for Maximizing Student Development (IMSD T32 training grant) and the Institute for Strategic Enhancement of Educational Diversity (iSEED) program. To increase yield on admission offers, we award a number of internal fellowships (such as Schomburg, Presidential, and Graduate School fellowships) that provide funds on existing assistantship packages. These funds allow us to increase funding offers for these highly sought-after students.

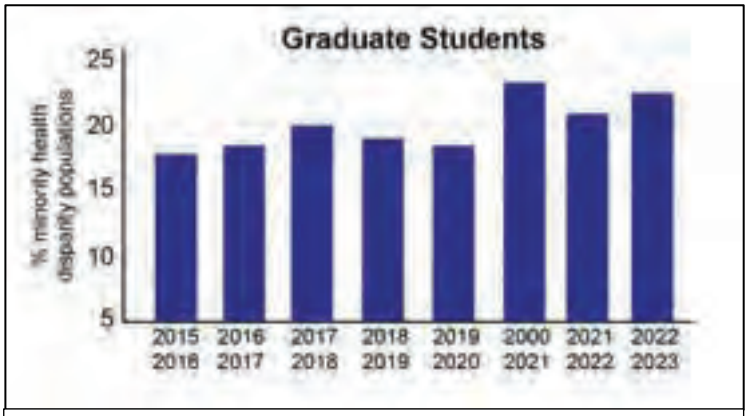


Figure 2. Percent of graduate students admitted who are members of minority health disparity populations or other health disparity populations by year.

Figure 2 shows the percentage of graduate students admitted who are members of NIH-designated minority health disparity populations or other health disparity populations by year.

The **Collaborative Learning and Integrated Mentoring in the Bioscience (CLIMB)** Program has been particularly successful in recruiting students form diverse backgrounds into graduate programs, both locally and nationally. Founded in 2009, CLIMB offers research opportunities, mentoring, and professional development workshops to undergraduates, graduates and postdocs and has had (as of 2022) 588 participants (Current students 44% underrepresented minority [URM]). As of 2022, CLIMB UP has hosted 255 undergraduate students (68% URM) for summer internships. Of these, 103 (40%) have completed or are enrolled in PhD (28), MD (26), MD/PhD (3), Masters (13), DDS (9), PharmD (13), MPH (7), and other (4) programs. Overall, 37 are in UB programs and 66 are at other universities. **The CLIMB Program has received national recognition, including the 2020 Inspiring Programs in STEM Award from Diversity Magazine.**

Undergraduate Students in the School of Medicine

The School of Medicine includes an active undergraduate program in the biomedical sciences with approximately 1,000 students. The undergraduate program has eight majors, including:

- Biochemistry
- Biomedical Informatics
- Biomedical Sciences
- Biotechnology
- Medical Technology
- Neuroscience
- Nuclear Medicine Technology
- Pharmacology and Toxicology

Many graduates go on to professional or graduate school for advanced training. However, many are also placed in industry in a wide variety of fields, including healthcare facilities, biotech, or research labs.

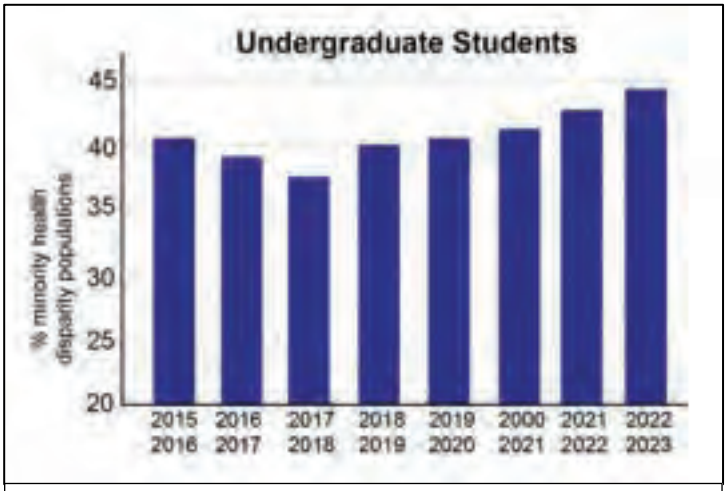


Figure 3. Percent of undergraduate students who are members of NIH-designated minority health disparity populations or other health disparity populations admitted to the School of Medicine by year

Figure 3 shows the percentage of undergraduate students who are members of NIH-designated minority health disparity populations or other health disparity populations admitted to the School of Medicine by year

Federal Pell Grants are awarded to undergraduate students who display exceptional financial need and have not yet earned a bachelor's degree. Of undergraduate students in the School of Medicine, 35.7% are Pell Grant eligible in the 2022-23 academic year, reflecting efforts to admit students from underrepresented groups:

- Total undergraduate students: 1,036
- Pell Grant eligible: 370
- % Pell Grant eligible: 35.7%

University-wide demographics of students

UB has launched and implemented robust and broad-based programs to enhance the diversity of students, faculty, and staff (summarized below). These efforts have resulted in a 40% increase over the last 10 years in the percentage of NIH-designated minority health disparity populations or other health disparity populations in the overall student population at UB (**Table 1).**

Table 1. Demographics of All Undergraduate, Graduate, and Professional Students at University at Buffalo

Students	2012-13 academic year		2022-23 academic year	
	Number	Percentage	Number	Percentage
NIH-designated minority health disparity populations or other health disparity populations	6,355	23.6%	10,209	33.1%
Total students	26,961[1]		30,877[2]	

[1]1,991 with unknown race subtracted from 28,952 total students
[2]1,122 with unknown race subtracted from 32,009 total students

Mentoring Programs to Support Successful Education and Completion of Degree

UB hosts many programs to support underrepresented and underserved populations. The programs are designed to support success, help build an interdisciplinary and diverse community at UB, and assist students to complete their programs and receive their degrees. These programs include:

- **Arthur O. Eve Educational Opportunity Program (EOP)** is a multifaceted academic and student enrichment program for students who have demonstrated their potential to academically and personally succeed at UB, despite economic or social barriers.
- **Access to College Excellence (ACE)** provides support services to students during their transition to college and throughout their first two years of study at UB.
- **Daniel Acker Scholars Program** is a community of academically talented, diverse students who demonstrate strong leadership potential and commitment to community service.
- **Collegiate Science and Technology Entry Program** (CSTEP) empowers talented undergraduate students from underrepresented backgrounds to pursue careers in science, technology, math, and engineering (STEM), the licensed professions and health-related fields.
- **McNair Scholars Program** serves low-income, first-generation students and traditionally underrepresented undergraduate student populations in PhD programs. Scholars have access to a network of year-round support that includes graduate school preparation, funded research opportunities and academic and personal development.
- **TRiO Student Support Services** support undergraduate students who are first-generation, low-income, and/or students with disabilities to help them overcome academic, cultural and social barriers so they can succeed in higher education. Students receive holistic academic and personal support services designed to assist with graduate school and career preparation, economic and financial literacy, and ultimately persistence to graduation.
- **Arthur A. Schomburg Fellowship** is a graduate fellowship program that supports high achieving students who contribute to the diversity of campus. The program includes professional development opportunities and cross-disciplinary community building experiences to enhance graduate experience. This program is funded by SUNY.
- **Generation Honors** program offers an opportunity for Honors Scholars from underrepresented backgrounds to develop a deep sense of community, build lasting connections and leverage key campus resources starting the summer before freshman year and lasting through graduation. In Fall 2022, **42** students participated in this program, a **120%** increase over 2021. Among the top

40 public university honors colleges, Generation Honors is the only summer bridge cohort program prioritizing underrepresented students of which we are aware.

UB has a high number of first-generation students, 20% of the undergraduate population. As part of a larger program by the Association of Public and Land-grant Universities (APLU) initiative to close the achievement gap for underrepresented minority and underserved undergraduates, UB has developed summer bridge and peer mentoring programs for first gen students:

- **First Gen Peer Mentoring Program** provides mentorship from an upperclassman and support to first-generation college students for their first year at UB
- **UB Thrive** is a summer bridge program for STEM and first-generation students. For summer 2021, **92%** of STEM Success participants were retained to the second semester, and **97%** of first generation students were retained to second semester. The program was particularly impactful for underrepresented minorities (URM), women, and Pell student retention:
  - **100%** of **URM** participants retained to their second term
  - **100%** of **Women** participants retained to their second term
  - **94%** of **Pell Eligible** participants retained to their second term

University-wide Programs to Increase Faculty Recruitment of Minority and Other Members of Health Disparities Populations

Recognizing that a diverse, equitable and inclusive community is an essential foundation for achieving excellence and success, the University at Buffalo has long been committed to fostering diversity, inclusivity, and accessibility on campus. Founded in 1846, UB's integration into the SUNY system in 1962 coincided with a period of deep social and academic engagement on campus with local and national civil rights struggles. That period witnessed the development of a commitment to addressing social issues and engagement with communities locally and globally that remains a hallmark of UB's culture.

UB was a pioneer in the establishment of race and gender studies programs in the late 1960s and early 1970s. Today, researchers, departments and schools across UB boast strengths in diversity and inclusion-related research and education, such as our national leadership in critical race, critical class and feminist legal theory in the School of Law; universal design in the School of Architecture and Planning; women's health in the School of Public Health and Health Professions; Africana and American studies, Asian studies, Jewish thought, disability studies, and global gender and sexuality studies in the College of Arts and Sciences; and race and equity in schools and society in the Graduate School of Education, to name just a few. In 2020, the College of Arts and Sciences, in collaboration with the Office of the Vice Provost for Inclusive Excellence, received a $3.2 million grant from the Andrew W. Mellon Foundation to launch the interdisciplinary Department of Indigenous Studies, which builds on UB's longstanding legacy as a key location for Haudenosaunee and Indigenous studies.

In 2014, UB founded the Office of Inclusive Excellence. Led by the Vice Provost for Inclusive Excellence, UB's chief diversity officer, the office is responsible for facilitating UB's diversity and inclusion strategies and for supporting UB's efforts to provide an inclusive campus culture. A pioneer within SUNY in launching an office focused on equity and inclusion and in creating a cabinet-level, chief diversity officer position, UB was a model for the entire system when SUNY launched its multi-prong effort in 2015 to address diversity and assure inclusive excellence system-wide. In 2019, UB created a university-wide network of 16 unit diversity officers, who represent each of UB's schools and several administrative offices and who work with the Vice Provost for Inclusive Excellence. The unit diversity officers are a national model for coordinating efforts and sharing resources across a large university, which recognizes the needs of the individual colleges and units while, at the same time, providing a mechanism for collaboration for university-wide impact.

In 2019, UB president Satish Tripathi established an ambitious goal to move UB into the top 25 public research universities in the nation. A key goal of UB's Top 25 institutional ambition is to further enhance faculty and student diversity through focused enrollment and hiring strategies and the implementation of best practices that further integrate inclusiveness into all aspects of the university. UB is committed to doubling the number of faculty from historically underrepresented backgrounds between 2020 and 2025. In support of this effort, several individual schools have launched or grown faculty pipeline programs. University-wide, in 2020-21, UB launched the

Distinguished Visiting Scholars program, among the largest and most comprehensive program of its kind, which brings a cohort of highly accomplished scholars and artists whose work elucidates social inequality and advances social justice for the university and Buffalo community.

- **Distinguished Visiting Scholars Program.** UB provides a one-year, temporary, full-time, residential, salaried position (benefits eligible) as a Distinguished Visiting Scholar hosted by a department within the College of Arts and Sciences. Distinguished Visiting Scholars will be part of a cohort. The program provides scholars and artists of exceptional accomplishment a unique opportunity to join a cohort of visiting faculty to promote diversity, equity, and inclusion. The program has led to recruitment of several new full-time faculty. The first cohort was 2020-21 and three cohorts of ~10 scholars each year have participated. Ten scholars have committed to the 2023-24 cohort, which will be the fourth cohort of this highly successful program.

In fall 2021, the Office Inclusive Excellence launched the Visiting Future Faculty (VITAL) program, which brings late-stage PhD scholars from historically underrepresented groups to UB to present work and engage with community**.**

- **Visiting Future Faculty Program** (VITAL) is a four-day program that brings outstanding doctoral scholars from all disciplines to UB. VITAL contributes to the growth of faculty from traditionally underrepresented populations in the United States, particularly from Indigenous, African American/Black, and Hispanic/Latinx backgrounds. VITAL scholars present their work, engage with UB faculty and students, meet other scholars in the program, and experience the region's many offerings. The first cohort was in 2022 in which 22 scholars from throughout the country visited UB. Recruitment is underway for the 2023 cohort to start in October.
- **PRODiG ("Promoting Recruitment, Opportunity, Diversity, Inclusion and Growth")** is a SUNY-wide program to increase underrepresented faculty at SUNY in all disciplines and women in STEM fields. Supported by $2,199,600 in PRODiG funds since 2019, UB hired 26 new faculty, including 12 from underrepresented backgrounds (including 3 women in STEM) and 14 women in STEM fields.

As a result of these and other efforts, the percentage of historically underrepresented faculty among new tenured and tenure-track hires has increased from 8% in 2017 to ~36% in 2022.

Leadership Hires

During the last two years, UB recruited new Deans of four of the six Health Sciences Schools. Two are women (medicine- Dean Allison Brashear and nursing- Dean Annette Wysocki) and the others are African American (social work- Dean Keith Alford) and Latinx (dental medicine- Dean Marcelo Araujo). UB is committed to diversifying students, faculty, staff, and university leadership.

In 2020, President Satish K. Tripathi formed the President's Advisory Council on Race (PACOR) to ensure equity in UB's policies, programs, activities and traditions. To date, more than 150 faculty, students and staff have been involved in efforts to address critical issues relevant to curriculum; pedagogy; faculty and staff hiring, retention and advancement; enrollment; the campus experience; and community engagement. Ongoing implementation of the PACOR recommendations is a top priority for the university.

Developing Early Career Pathways

As part of our underlying theme of prioritizing health equity at our university, we are committed to training a workforce prepared to confront the structural racism that generated centuries of disparate health outcomes. A critical element to achieving diversity at the faculty level is establishing early pathways to science careers in groups underrepresented in science and medicine. The student population in Buffalo Public Schools, the second largest school district in the state, is 80% underrepresented minority and has one of the lowest high school graduation rates in the state. UB has placed a priority on developing career pathways beginning with elementary schools in Buffalo Public Schools through the faculty level. **Table 2** (next page) briefly outlines the many programs and initiatives of UB faculty and students at the elementary, middle, and high school levels in developing career pathways for academic and career success, with a focus on Buffalo Public Schools.

Table 2. University at Buffalo career pathway programs to enhance the diversity and excellence of the pool of future trainees and faculty

Level	Program	Host/Funding Source	Participants	Remarks
Elementary School	Black Men in White Coats	UB medical student volunteers	Elementary students in *Buffalo Public Schools*	Mentoring by medical students
Elementary School	Microbiome Workshops	UB Genomics, Environment and Microbiome Community of Excellence	Second graders in *Buffalo Public Schools*	Delivered by UB faculty and graduate students to *Buffalo Public Schools*
Middle School	Interdisciplinary Science and Engineering Partnership (ISEP)	$10 million NSF grant: Interdisciplinary Science and Engineering Partnership (ISEP)	Middle Schools in *Buffalo Public Schools* (Goal: transform how science is taught)	Mentoring and teaching in STEM by UB faculty and students and develop classroom materials
Middle School	Annual Genome Day	Center of Excellence for Bioinformatics and Life Sciences and ~50 UB student and faculty volunteers	Eighth graders from *Buffalo Public Schools*	Hands-on laboratory experience in UB labs for 400 eighth graders annually
Middle School and High School	Science and Technology Entry Program (STEP)	New York State Department of Education, UB Cora P. Maloney Center	Underrepresented and economically disadvantaged students in *Buffalo Public Schools*	Tutoring to prepare students to enter college in STEM. (42 students per year grades 7-12)
Middle School and High School	Geo-Technology Experiences for Students and Teachers (GTEST)	$10 million NSF grant: Interdisciplinary Science and Engineering Partnership (ISEP)	Middle and high school students and teachers in high-needs school districts	Summer camp experience and after school program for teachers and students
Middle School and High School	Curriculum on genome and microbiome science	UB Genomics, Environment and Microbiome Community of Excellence	*Buffalo Public School* students	Faculty and graduate students work with teachers to develop lessons in genome and microbiome education
Middle School, High School, and parents	Buffalo Niagara Medical Campus Open House	Center of Excellence for Bioinformatics and Life Sciences and institutions of the Buffalo Niagara Medical Campus	*Buffalo Public School* students and parents	Participants visit institutions on the campus and participate in hands-on learning activities.
High School	Scientific Educational Partnership Award (SEPA)	NIH R25 GM 137364 Metagenomics Partnership Project and New York State Area Health	*Buffalo Public School* students and teachers	Pathway to recruit students to careers in health care and STEM. Hand-on training for science teachers in metagenomics and bioinformatics.

		Education Center System (AHEC)		
High School	Paid summer research internships in UB labs	Center for Bioinformatics and Life Science and faculty volunteer mentors	Students in *Research Laboratory High School*, a new Buffalo Public School	Through the Erie County "Summer Youth Employment Program," the Buffalo Urban League, and the UB partnership with this new Buffalo Public school, students are placed in UB research labs
High School	After School Program to Support Extended Learning	*Buffalo Public Schools*	High school students in *Buffalo Public Schools*	Tutoring and mentoring high school students
High School	STEM Literacy Program	Subaward, *Buffalo Public Schools*	High school students in *Buffalo Public Schools*	With Department of Surgery
High School	UB-*Buffalo Public School* Partnership to Improve Student Achievement in Biological Sciences	Cullen Foundation	High school students in *Buffalo Public Schools*	Tutoring and mentoring in biological sciences
High School	Science Education Fellows	Cullen Foundation	*Buffalo Public School* teachers	UB students (Science Ambassadors) work with *Buffalo Public School* teachers to create educational materials on health sciences
High School	Science Exploration Day	UB faculty and students	*Buffalo Public School* teachers	Day-long science and engineering talks and activities in 3 concurrent sessions
High School	Health Science Symposium for high school juniors	Department of surgery with Roswell Park Comprehensive Cancer Center, Hauptman Woodward Institute, Kaleida Health and local health science companies	High school juniors in *Buffalo Public Schools*	Day-long event on all aspects of health sciences, including surgery, dentistry, research, drug development, and infection control.
High School	Buffalo Niagara Medical Campus Summer STEM Program	School of Medicine, Buffalo General Medical Center, Oishei Children's Hospital, UB Clinical and Translational Research Center,	*Buffalo Public Schools*	Two-week hands-on workshops for entering high school students to *Buffalo Public Schools*. Students visiting institutions on the Buffalo Niagara Medical Campus

		Roswell Park, several biotech companies		
High School	Liberty Partnership Program	New York State and UB Cora P. Maloney Center	*Buffalo Public Schools*	Goal is to increase the high school graduation rate in *Buffalo Public Schools*. Academic support, individual and family counseling, career guidance, and parent engagement
High School	UB Upward Bound Program	United States Department of Education, UB Cora P. Maloney Center	High school students from disadvantaged backgrounds	Academic immersion, service learning, civic engagement, career exploration, creative thinking, hands-on discovery and personal growth

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Timothy Middle Name Last Name*: Murphy Suffix: M.D.

Position/Title*:
Organization Name*: STATE UNIVERSITY OF NEW YORK AT BUFFALO
Department:
Division:
Street1*: 875 Ellicott St.
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1034

Phone Number*: (716) 881-8911 Fax Number:

E-Mail*: murphyt@buffalo.edu

Credential, e.g., agency login: tmurphy

Project Role*: PD/PI Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Murphy_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Oscar Middle Name Last Name*: Gómez Suffix: Ph.D

Position/Title*: Associate Professor and Division Chief
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 1001 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1009

Phone Number*: (716) 323-0150 Fax Number:

E-Mail*: oscargom@buffalo.edu

Credential, e.g., agency login: GOMEZOSCAR

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Gomez_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Susan Middle Name Last Name*: Grinslade Suffix: Ph.D

Position/Title*: Associate Director
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 210 Wende Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3079

Phone Number*: 716-829-2234 Fax Number:

E-Mail*: msgrinsl@buffalo.edu

Credential, e.g., agency login: MGRINSLADE

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Grinslade_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Ekaterina Middle Name Last Name*: Noyes Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 270C Farber Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8001

Phone Number*: (716) 829-5386 Fax Number:

E-Mail*: enoyes@buffalo.edu

Credential, e.g., agency login: Knoyes17

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Noyes_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Heather Middle Name Last Name*: Orom Suffix: Ph.D

Position/Title*: Associate Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 304 Kimball Tower
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8028

Phone Number*: (716) 829-6682 Fax Number:

E-Mail*: horom@buffalo.edu

Credential, e.g., agency login: ay6457

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Orom_Bio_.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Rev. First Name*: Kinzer Middle Name Last Name*: Pointer Suffix:

Position/Title*:
Organization Name*: Concerned Clergy Coalition of Western New York
Department:
Division:
Street1*: 347 Peckham Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14206-1716

Phone Number*: 716-563-1609 Fax Number:

E-Mail*: kinzerpo@buffalo.edu

Credential, e.g., agency login: KINZERPO

Project Role*: Other (Specify) Other Project Role Category: Collaborator

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Pointer_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Robert Middle Name Last Name*: Silverman Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 329 Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8030

Phone Number*: (716) 829-5882 Fax Number:

E-Mail*: rms35@buffalo.edu

Credential, e.g., agency login: SILVERMAN35

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Silverman_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Christopher Middle Name Last Name*: St. Vil Suffix: Ph.D

Position/Title*: Assistant Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 625 Baldy Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14260-1000

Phone Number*: 716-645-9091 Fax Number:

E-Mail*: cstvil@buffalo.edu

Credential, e.g., agency login: CSTVIL

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: St.Vil_Bio_.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Henry Middle Name Louis Last Name*: Taylor Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 330A Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8030

Phone Number*: (716) 829-5458 Fax Number:

E-Mail*: htaylor@buffalo.edu

Credential, e.g., agency login: HLTAYLOR

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Taylor_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Carol Middle Name Last Name*: Van Zile Tamsen Suffix: Ph.D

Position/Title*: Director
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 5A Norton Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14260-1800

Phone Number*: (716) 645-3905 Fax Number:

E-Mail*: cmv3@buffalo.edu

Credential, e.g., agency login: CAROLVAN

Project Role*: Other (Specify) Other Project Role Category: Evaluator

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Van_Zile-Tamsen_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Gregory Middle Name Last Name*: Wilding Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 719 Kimball Tower
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8028

Phone Number*: (716) 829-2594 Fax Number:

E-Mail*: gwilding@buffalo.edu

Credential, e.g., agency login: gewilding

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Wilding_Bio.pdf

Attach Current & Pending Support: File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 01/31/2026

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	Aims_Overall.pdf
3. Research Strategy*	0verall_Research_Strategy.pdf
4. Progress Report Publication List	
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	Letters_of_Support.pdf
10. Resource Sharing Plan(s)	
11. Other Plan(s)	Data_Management_and_Sharing_Plan.pdf
12. Authentication of Key Biological and/or Chemical Resources	
Appendix	
13. Appendix	

Igniting Hope in Buffalo NY Communities: Training the Next Generation of Health Equity Researchers

A1. Specific Aims

Buffalo, New York, the second largest city in the state (population 278,349), has a diverse population, including 37% African American and 14% Latinx. One of the most pressing problems in metropolitan Buffalo is race-based health inequities, a condition shared with many American metropolitan areas. The life expectancy of African American residents of Buffalo is 10 to 12 years shorter compared to White residents of Buffalo (1). African Americans are 300% more likely to have chronic, often preventable, diseases than Whites who live in Buffalo (2, 3). These statistics reflect inequities due to systemic structural racism leading to differential health outcomes, resulting from the social determinants of health.

In response to this crisis, the African American Health Equity Task Force (Task Force) was formed in 2014, led by visionary community leaders from multiple sectors of the Buffalo community, including faith leaders, community non-profits, healthcare providers, payers and more. In addition, University at Buffalo (UB) faculty and the leadership of the UB Clinical and Translational Science Institute (CTSI) joined the Task Force when it was formed. The Task Force has met monthly since 2015 and led to the formation in 2019 of the UB Community Health Equity Research Institute and simultaneously the community-based Buffalo Center for Health Equity. Our UB Institute's goal is to *perform research to advance understanding of the root causes and develop and test innovative solutions to eliminate health inequities in the region.* After meeting with Task Force leaders, Erie County legislator April Baskin proposed legislation that created an Office of Health Equity in the Erie County Health Department of Health that was passed into law in 2021. A community leader, who is a member of the Task Force, was appointed director of the office. The four organizations are part of the Task Force, which continues to meet monthly (**Figure A1**). This ***community-university-government partnership*** has enormous reach and influence throughout the community, positioning us to disseminate research findings and work with policy makers and community stakeholders to promote sustainable community- and system level- change. This enduring partnership represents a strong foundation on which to establish an NIMHD Center of Excellence in Investigator Development and Community Engagement (Center of Excellence).



Figure A1. The African American Health Equity Task Force, which includes the four organizations above and many community stakeholders, meets monthly.

The mission of our Center of Excellence is to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community. We will train a workforce prepared to confront disparate health outcomes from centuries of structural racism and function with the expertise and support of our influential community partnerships. A diverse workforce is critical to enhancing the excellence, creativity and innovation needed to solve complex, systemic problems to reduce health inequities (4, 5). We will engage early-career investigators from all six UB health sciences schools (Medicine, Nursing, Public Health, Pharmacy, Dental Medicine, Social Work) and beyond (Architecture and Planning, Arts and Sciences, etc) enabling our Center to train a broad range of scientists in health disparities, mentored by experts from multiple disciplines. We will offer pilot studies in minority health and health disparities research and facilitate formation of a mentoring team for each pilot studies awardee. We will individually tailor support in research design, biostatistics, regulatory compliance, links with community partners and grant writing for each scholar, being responsive to our diverse investigators, who have different strengths and opportunities for growth. We will accomplish these Aims:

Aim 1. Inspire, train and mentor a new generation of scientists from diverse backgrounds and disciplines to advance their knowledge and to perform innovative research in health disparities.

Aim 2. Nurture our enduring community-university partnerships to perform transdisciplinary research to develop and test innovative solutions to end race-based health inequities in Buffalo.

Aim 3. Advance equitable collaborations with community partners to translate our research into sustainable, community and system-level changes toward eliminating race-based health inequities in our community and disseminate the results to community stakeholders and policy makers.

A2. Significance and Environment

Health disparities and health inequities are closely linked with racial and social justice. The term “disparities” refers to the disproportionate health outcomes by race while the term “health inequity” stresses the injustice and oppression that underlies these differences (6, 7). The undesirable health outcomes result from institutional and societal conditions that lead to the social determinants that result in adverse health outcomes.

Our proposed work is focused in a racially segregated urban setting, specifically East Side neighborhoods where most African Americans in Buffalo live (**Figure A2**). Buffalo is the sixth most segregated metro area in the United States (US) (8). Studies of health inequities explore the dynamics of the most destructive element of racial oppression in the US,— health inequity. In this proposal we commit ourselves to the battle to improve health outcomes for African Americans in Buffalo. Demonstrating and testing innovative approaches in our community will enable us to disseminate solutions that prove effective, given the reality that many American cities experience race-based health disparities.

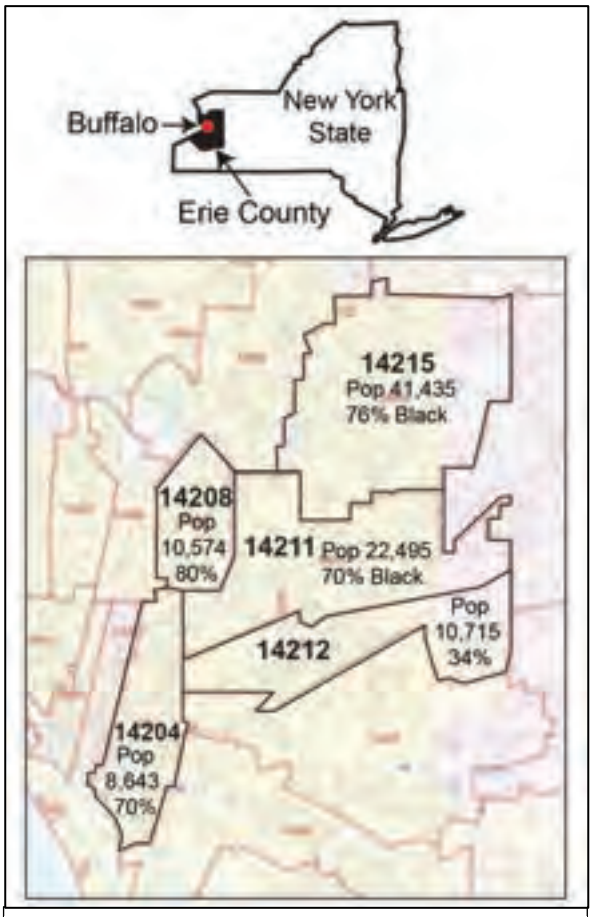


Figure A2. Map of five ZIP codes on Buffalo’s East Side, showing population (Pop) and percent of Black residents. Source: U.S. Census and Social Variables Database of Buffalo East Side - H. Taylor, UB Center for Urban Studies.

Table A1 shows the extraordinary race-based disparities in health outcomes in Erie County, where Buffalo is located. These data are striking, revealing a social tragedy, not simply because someone died before their time, but because these are stolen years robbing a community of what might have been. Premature death results in broken up families, and the loss mothers, fathers, sons and daughters, boyfriends, and girlfriends. It robs a community of a great leader who died before realizing their potential and a brilliant scientist who would have saved millions had she not died at birth. These data continuously remind us of the human toll of health disparities in our community.

Shifting the Community Engagement Paradigm

Universities and academic health centers have long considered community engagement as a social responsibility. A more comprehensive approach to working with communities is required to shift the narrative toward a more population health paradigm (9). It is important for universities and academic health centers to move from viewing communities as groups of people who have needs to recognizing them as assets. Engaged communities can better show institutional leaders and researchers how to understand and address social determinants of health (SDOH) and increase the impact of research discoveries (10). This is the approach that our NIMHD Center of Excellence in Investigator Development and Community Engagement (Center of Excellence) will take.

Table A1. Erie County Health Indicators by Race

Health Indicator	White	Black
% premature deaths (<75 years)	36%	60%
Heart disease mortality per 100,000	174	209
Stroke mortality per 100,000	33	48
Diabetes mortality per 100,000	20	44
Diabetes hospitalization per 100,000	13	50
Asthma hospitalization per 10,000	10	47
% Low birthweight births (2500 grams)	7%	14%
Infant mortality per 1000 live births	4.7	11.3
Source: New York State Department of Health, County Health Indicators by Race/Ethnicity 2016-2018		

Community engagement is too often dependent on individual faculty or student led programs. With this approach, programs dissolve when the people leading them leave and the trust that was built with the community is lost, creating a cycle of mistrust. This reality emphasizes the importance of central structures in universities devoted to community health equity. A Center of Excellence grant to attract and train new faculty into health disparities research working with the UB Community Health Equity Research Institute will provide stability and sustainability to our centralized structures enabling authentic, sustainable community engagement. Our Community Engagement and Dissemination Core is designed to empower the community as true collaborators and partners, enabling us to elevate the impact of research discoveries creating sustainable changes to achieve health equity. We will leverage our exceptional community-university-government

partnership (see Overall Aims page) for the research of investigators supported by our Center of Excellence to be disseminated to the community and implemented to benefit the community.

Diversifying our Workforce through a Transformational Institutional Hiring Initiative

A diverse workforce is critical to solving the complex, systemic problems to reduce health inequities (11, 12). A key element to achieving diversity among researchers and research leaders is establishing early pathways to science careers in groups underrepresented in science and medicine. The student population in Buffalo Public Schools, the second largest school district in the state, is 80% underrepresented minority and has one of the lowest high school graduation rates in the state. UB placed a priority on developing career pathways through the faculty level, beginning with elementary schools in Buffalo Public Schools. (see Investigator Development Core and Special Eligibility Requirement attachment)

In 2022, UB was designated as one of two flagship universities of the SUNY system of 64 campuses. As a result, New York State has made a historic investment to grow the ranks of tenure-track faculty at UB. In a transformational initiative, UB will be hiring ~200 new tenure-track faculty over the next few years (see President/Provost letter). In 2020, UB committed to doubling the number of faculty from historically underrepresented backgrounds by 2025. As signs of early progress, while 10% of faculty hires in 2019 were from underrepresented backgrounds, the rate steadily increased to more than 25% in 2022. A prime example is Dr. Jamal Williams, born and raised on the East Side of Buffalo:

Jamal Williams PhD was born and raised on the Buffalo's East Side and attended Buffalo Public Schools. He earned his PhD in Neuroscience from UB in 2022. He was supported by CLIMB program (Collaborative Learning and Integrated Mentoring in the Biosciences) and Institute for Strategic Enhancement of Educational Diversity (iSEED) Fellowships and two NIH diversity supplements. His PhD thesis focused on epigenetic mechanisms of cognitive decline in Alzheimer's disease and related neurodegenerative disorders. He published 12 papers from his PhD work, several in high impact journals, and has won numerous awards for his research. He earned an NIH D-SPAN Blueprint F99/K00 Award (F99NS118745) and did a postdoctoral fellowship with Dr. Daniel Geschwind at UCLA, a pioneer and international authority in the functional genomic analyses of the nervous system.

Dr. Williams was recruited to a tenure-track position at UB as Assistant Professor of Psychiatry in 2023. He is working on the genetics of neurodevelopmental disorders (autism) particularly in diversifying genetic databases in which people of African descent are profoundly underrepresented. He has created extensive partnerships in East Side neighborhoods. PI Murphy is chairing his mentoring committee, which also includes Steven Dubovsky MD, the UB Chair of Psychiatry, and Ray DePaulo MD of Johns Hopkins, an internationally recognized expert on the genetics of depression, bipolar disorder, and other mental health disorders.



Jamal Williams PhD

Faculty in our Center of Excellence will be actively involved in recruiting new faculty as part of this hiring initiative (see Dean and VP for Health Sciences letter). We will leverage the outstanding resources of our proposed Center of Excellence including mentoring, didactic training, a peer group, pilot studies, grant writing support etc., to recruit diverse faculty with expertise in health disparities research to UB (see Investigator Development Core).

Endowed Chair in Health Equity

The UB Provost committed to supporting a Carl Granger Endowed Chair in Health Equity who will also serve as the Director of the UB Community Health Equity Research Institute (see President/Provost letter). This huge investment gives us the opportunity to recruit a national leader in health equity research with hopes to further enhance and grow the mission of the Health Equity Institute of performing research to achieve health equity in our community. This exciting prospect is further evidence of the strong and growing commitment of UB to eliminate the disturbing health disparities in our community.

Equitable Stakeholder Collaborations: Creating Sustainable, Systemic Change

A priority of our proposed Center of Excellence is the emphasis on catalyzing sustainable, systemic change in health inequities and social determinants of health in Buffalo. Too often, academic researchers end their involvement after publishing their work and completing their grant. Our Community Engagement and Dissemination Core will work with each early career investigator in enabling the results of their work to lead to systemic change, particularly through policy changes. A community representative with relevant connections to the work will be included on mentoring committees to work with pilot studies awardees in designing and implementing pilot studies projects. Three examples of how our community partnerships are addressing race-based inequities and creating early change in our community are noted:

- Awareness of race-based health inequities by community stakeholders. Following the release of a comprehensive report in 2014 on the striking health disparities in African Americans in Buffalo (13), the African American Health Equity Task Force determined that a community dialogue was needed to create awareness and focus research and advocacy on the root causes of these disparities. In response, a team of community leaders and university faculty organized the annual *Igniting Hope* conference series that has become the premier conference on health disparities in the region (14). The series, supported by an NIH R13 conference grant (R13 TR003486) from 2020-2023, has been held five times (2018-2022) and attracts 250 to 300 attendees each year, including community leaders, community members, university faculty and trainees. It will next be held September 30, 2023. Approximately half of attendees are community members and half are university faculty and trainees (**Figure A3**). The conference includes keynote talks by national leaders in health disparities and breakout groups. The conferences are attracting the attention of elected leaders, business leaders and policy makers, creating awareness of the pervasive health inequities in East Side neighborhoods that are often too easily ignored. For example, the Deputy Mayor of Buffalo, State Senator Tim Kennedy and many other community leaders now attend the conference. Awareness of the problem communicated by credible sources to stakeholders is a critical step toward policy change.

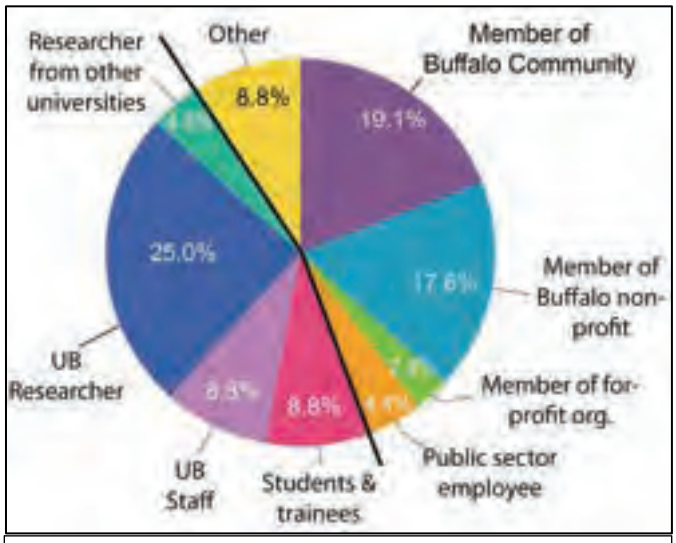


Figure A3. Breakdown of attendees of the 2021 Igniting Hope Conference

- Fines and fees reform. A discussion in a breakout group in the 2018 Igniting Hope conference, led to the formation of a working group on fines and fees that partnered with the Western New York Law Center to address the problem of disparate traffic ticketing in predominantly African American East Side neighborhoods resulting in suspension of a person's driver's license when they can't afford to pay a traffic ticket. African Americans are disproportionately stopped and ticketed, creating a cycle of debt and punishment that especially burdens low-income communities of color. The Task Force co-hosted a series of "community conversations" which attracted attention from the media and led to a series of articles in the Buffalo News and Investigative Post, raising further attention to the problem at the state level. New York State Senator Tim Kennedy, who represents Buffalo's East Side and works closely with the Task Force, co-sponsored a bill (Senate Bill S5348B) that was passed in the 2019-2020 legislative session and signed by the governor to reform the law related to driver's license suspension. This new law has substantially reduced traffic tickets and driver's license suspensions in East Side neighborhoods. The efforts of the working group created from the *Igniting Hope* conferences contributed to this policy change and outcome by bringing attention to the problem and engaging elected leaders.

- Mitigating the disproportionate fatalities in African Americans during the COVID pandemic. African Americans throughout the US were more likely to contract COVID-19 and more likely to die from COVID-19 compared to the general population (15-18). The city of Buffalo was a prime example of this disproportionate impact. On April 9, 2020, 67% of COVID-19-related deaths in Buffalo were in African Americans while the city's overall population is 37% African American. In response, our community-university partnership worked with Erie County leadership on a comprehensive community-based effort to mitigate the disproportionate impact in East Side communities. We worked with the Visiting Nursing Association of Western NY to set up mobile COVID-19 testing sites in East Side neighborhoods. Supported by a grant from Erie County, call centers based in 15 churches reached out to families to assess their needs and connected them with services and support, including masks, meals, accurate information, and transport to testing sites and healthcare. Remarkably, seven weeks later, on May 28, 2020, 45% of deaths in Buffalo from COVID-19 were in African Americans (down from 67%) compared to 37% of the overall population. Buffalo is one of few communities in the country that was able to reduce and sustain the reduction in the disparity in fatality rates in African Americans to this degree, an achievement that is a direct result of a strong partnership and collaboration between the community, the university, and the county.

This work and outcomes were important in influencing County Legislature Chairwoman April Baskin and County Executive Mark Poloncarz to establish the Erie County Office of Health Equity in 2021. Kelly Wofford, an active member of the Buffalo Center for Health Equity was appointed Director of the Office of Health Equity. We will continue working together for sustainable changes to improve health equity in Buffalo. (see Letters of Support).

A3. Innovations

- ***Influential, enduring community-university-government partnership.*** This key partnership has resulted from a nine-year commitment by all parties to work together in the fight to eliminate race-based health inequities in Buffalo. The trust and lines of communication we built together were invaluable in responding quickly and definitively to the disproportionate impact of the pandemic on communities of color. This extensive reach and influence throughout the community will position us to translate findings into sustainable community and system-level changes locally and nationally through sharing our solutions.
- ***Innovative approaches to advance DEIA*.** Our Center of Excellence has a comprehensive commitment to diversity, equity, inclusion, and accessibility (DEIA) through undertaking intentional steps to diversify our workforce and creating an inclusive, welcoming culture with an innovative DEIA action plan. We will leverage the ongoing hiring initiative to participate actively in recruitment to increase faculty diversity and expand the faculty who work in minority health and health disparities research. (see Investigator Development Core)
- ***Embedding of the Center of Excellence in the Community Health Equity Research Institute.*** The Health Equity Institute includes faculty from all 12 UB schools, creating a transdisciplinary framework that cuts across scientific and organizational silos to integrate disciplines, including biomedical, behavioral, and social sciences; epidemiology; data science; public health; health services; economics; public policy; and more. This relationship with the Health Equity Institute will provide a large pool of excellent mentors to enable our scholars to take on projects that use approaches encompassing multiple domains of influence and multiple levels of influence, aligning with the NIMHD Research Framework (see Administrative Core).
- ***Emphasis on sustainable community- and system level-change.*** Academic researchers often view their work as completed when they publish the results in a scientific journal. One of the most frequent questions our community partners ask when they meet with faculty researchers is “How will your research benefit us as community members?” A priority of our Center of Excellence is to translate the results of our research into sustainable change (Aim 3 in Overall). Realistically, pilot studies-sized projects alone will not create systemic change. However, an important goal of our pilot studies is to provide results leading to larger grants to tackle generational challenges. Our Community Engagement and Dissemination Core will work with scholars to put their project on a path toward research that creates sustainable change to benefit the community. The Erie County Office of Health Equity is positioned to make policy recommendations as a result of research findings.
- ***Pre-existing working relationships with elected leaders and policy makers.*** Our team has worked actively with community leaders, including elected leaders, to enact changes in laws, policies, and practices to address SDOH in our community. These are noted throughout the proposal and in letters from city (mayor), county (county executive and Office of Health Equity Office Director), state (state senator) and federal (congress member) leaders. These relationships are key in translating our work into system-level changes.
- ***Close partnership with the Clinical and Translational Science Institute (CTSI).*** The vision of the UB CTSI is “to advance and accelerate research to reduce health disparities and improve the health of our community and the nation,” aligning closely with this Center of Excellence. Dr. Murphy is PI of both; Dr. Gomez, who leads the Investigator Development Core, is associate lead of the CTSI KL2-mentored career development program, and Dr. Ekaterina Noyes, a Co-I on the Investigator Development Core is Director of CTSI Workforce Development. The CTSI offers extensive resources and expertise to UB research teams.
- ***Integration of community members into Center of Excellence leadership***. Community members play leadership roles in each core. Pastor George Nicholas, CEO of the Buffalo Center for Health Equity, is Center of Excellence Co-Director. Pastor Kinzer Pointer, President and CEO of Greater Buffalo United Ministries and mentor in the National Medical Association is Associate Director of the Investigator Development Core. Pastor Pointer and Dr. Murphy met with Congressman Brian Higgins of Buffalo and NIMHD Director Dr. Eliseo Pérez-Stable in Washington in March 2020 to discuss our work with the community (see letter of support). Rita Hubbard Robinson JD, an influential community leader serves on the Steering Committee. Stan Martin, Director, CAI Buffalo Office, Racial and Ethnic Approaches to Community Health (REACH), is Co-Director of the Community Engagement and Dissemination Core. These community leaders all receive support on this proposal in amounts on par with faculty effort. We take this approach with all our projects and publications together: community members are equal partners who are compensated on par with faculty.

A.4. Monitoring Progress and Evaluation

A logic model and a detailed monitoring and evaluation plan are described in the Administrative Core.

A5. Design, Structure, and Governance of the Center of Excellence

Our Center of Excellence is embedded in the UB Community Health Equity Research Institute, a fully sanctioned university-wide institute founded in 2019 as a direct result of our partnership and work with the African American Health Equity Task Force. The Center of Excellence will enable us to advance a critical element of our work toward eliminating health inequities by training new investigators in the discipline to take new approaches and become future leaders. A major advantage of this relationship is that early career investigators will have immediate links to the community to work together on projects and easy connection with researchers from multiple disciplines throughout UB for collaboration and expertise.

The governance structure has clear reporting lines and advisory groups representing key constituencies (see Administrative Core). We place emphasis on coordination and communication among the three cores. **Figure A4** shows a high-level view of the complementary Aims of the three cores and several examples in the center portion of the figure of coordination of activities among cores. Strategies to enhance communication among cores are listed at the bottom of the figure. The Administrative Core section describes this structure in more detail.

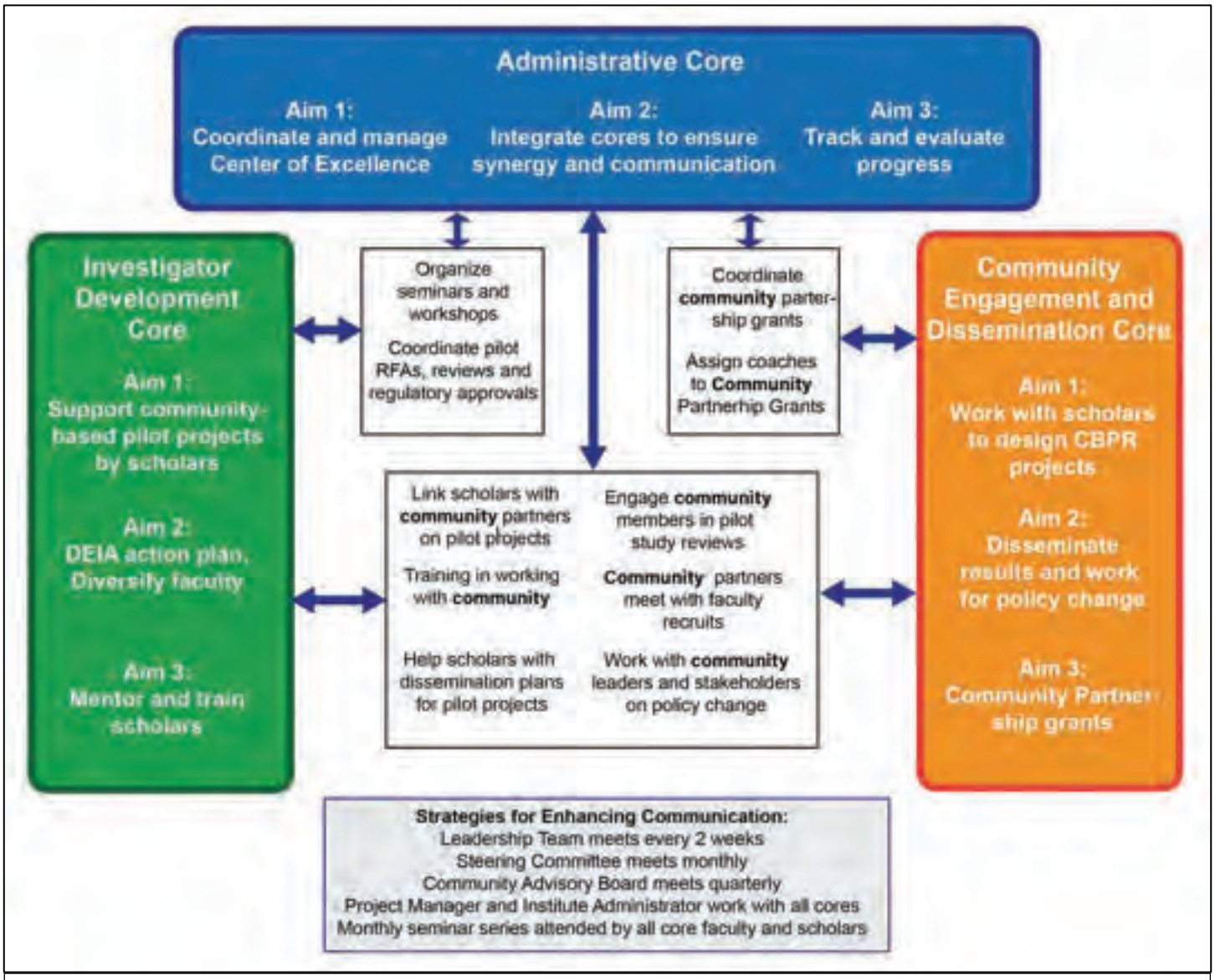


Figure A4. Coordination of Cores. DEIA: Dissemination, equity, inclusion, and accessibility; CBPR: community-based participatory research.

The Administrative Core of the Center of Excellence provides leadership and guides its overall vision. While the overlap in leadership between the Center of Excellence and the Health Equity Institute enhances coordination, communication, and collaboration, we are mindful of the related but separate missions of the two entities:

- **Center of Excellence mission:** To train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community.
- **Health Equity Institute mission:** To perform research to advance understanding of the root causes and develop and test innovative solutions to eliminate health inequities in the region.

The education and training components of the Center of Excellence will fill a critical gap in our minority health and health disparities research environment by bringing comprehensive and rigorous training and mentoring in the discipline. The CTSI and each of the UB health science schools have workshop series, seminars, and selected courses in health disparities research. The Center of Excellence will function as a centralized training center in health disparities research, bringing coordination and communication to this key element of advancing health disparities research locally and nationally. Further, the Center of Excellence will provide well-coordinated, careful mentoring, didactic training, and professional development individually tailored to each scholar's needs.

To be successful in performing research to advance community health, a pivotal skill for researchers is the ability to form equitable collaborative and sustainable relationships with community members. Our Center of Excellence will attract and train early-stage investigators to perform their research on health disparities based on the principles of community-based participatory research, an approach that engages the community as true partners in research, including guiding the research agenda, participating in the design and conduct of the research and benefiting from the results. Working with the Investigator Development Core our Community Engagement and Dissemination Core will work with each pilot study awardee to 1) provide training in working with the community, 2) link scholars with key community partners in the planning stages of their project, 3) develop a dissemination plan for their project to be implemented during the project and after it is completed, and 4) plan and implement an approach for their work to lead to actual benefit to the community. This often involves the planning of a larger project facilitated by the pilot study, which in many cases provides key preliminary data for the larger project.

In addition to training early career scientists in the science of health equity research, our training will also equip scholars in how to engage stakeholders and how to disseminate and translate new observations into sustainable change, (i.e., dissemination and implementation science). The Community Engagement Core and Dissemination will work with each scholar to develop a path toward sustainable change.

Summary and Vision

The year 2022 was particularly devastating for African American communities in Buffalo. While the community was recovering from the pandemic, which disproportionately impacted African Americans, a racially motivated shooting took place on May 14, 2022, on the East Side that tragically killed ten African Americans who were targeted specifically because of their race. Our community continues to be traumatized by this cruel tragedy. In December 2022, Buffalo experienced a deadly blizzard that killed 47 people, 25 African Americans. Of 199 people who visited Emergency Rooms with injuries due to the blizzard, 80% were African Americans (**Figure A5**). Sadly, this was a predictable outcome as many East Side residents live in old, substandard housing with poor insulation, limited internet access for communication and increased susceptibility to wind and snow damage reflecting disinvestment in a neighborhood impacted by a history of redlining and discriminatory lending. The pandemic, the May 14 racially motivated mass shooting and now the Blizzard of 2022 all highlight the profoundly adverse SDOH that African Americans in Buffalo experience. These tragic events fuel the fire of our community-university-government partnership to work together for fundamental, systemic change to address the underlying root causes and develop and test solutions to address the systemic causes. An NIMHD Center of Excellence in Buffalo will be an exceptional advance in this ambitious goal by attracting, training, and mentoring a new generation of researchers in the science of minority health and health disparities to create sustained improvements in health outcomes in African American communities in Buffalo and the nation.

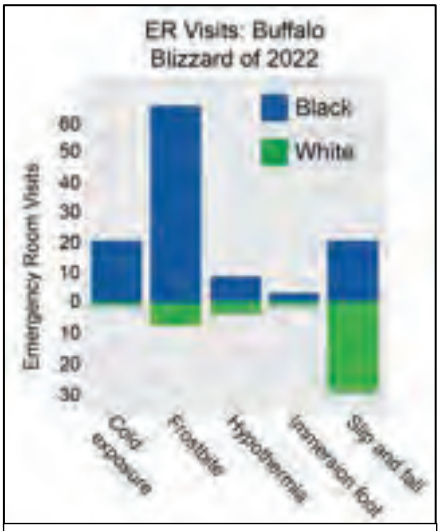


Figure A5. Race distribution of people who visited hospital ERs with cold-related injuries during the Blizzard of 2022.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	● Yes ○ No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
The form does not have any study records		

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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University at Buffalo
Community Health Equity Research Institute

Please find a table below on the letters of support for this proposal, *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers*, from the University at Buffalo.

INDIVIDUAL	TITLE	ORGANIZATION	PAGE #
Satish Tripathi, PhD & A. Scott Weber, PhD	President & Provost	University at Buffalo	1
Allison Brashear, MD, MBA	Vice President for Health Sciences and Dean	University at Buffalo, Jacobs School of Medicine and Biomedical Sciences	3
Pastor George Nicholas	CEO	Buffalo Center for Health Equity	5
Kelly Wofford	Director	Office of Health Equity, Erie County Department of Health	7
Stan Martin	Director	CAI Buffalo Office, Racial and Ethnic Approaches to Community Health (REACH)	9
Mark Poloncarz	County Executive	County of Erie, State of New York	11
Byron Brown	Mayor	City of Buffalo, State of New York	13
Tim Kennedy	Senator	State of New York	14
Brian Higgins	Congressman	United States Congress	15

University at Buffalo
Office of the President

July 13, 2023

Dr. Timothy Murphy
Clinical Translational Research Center
875 Ellicott Street
Buffalo, NY 14203

Dear Dr. Murphy:

We are very pleased to provide the full support of the University at Buffalo leadership for your proposal *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers* to the National Institute on Minority Health and Health Disparities. UB is strongly committed to advancing health equity in our region, and this award would enable us to achieve this by supporting research and training more researchers to address health disparities in our community.

In your role as Director of the UB Community Health Equity Research Institute, you have nurtured enduring partnerships with the community to work together to build programs and resources over the years to improve health equity in Buffalo and across Western New York. Your commitment has been unwavering. Your proposed NIMHD Center of Excellence in Investigator Development and Community Engagement has enormous potential to further advance the university's partnerships within our community and work toward eliminating health disparities. This Center of Excellence will be an outstanding resource for our faculty throughout UB, as more and more are embarking on projects with direct relevance to research in minority health and health disparities.

As part of UB's robust dedication to addressing health disparities in our region, we have committed funds to establish a Carl Granger Endowed Chair in Health Equity for the director of the UB Community Health Equity Research Institute. This significant investment gives us the opportunity to recruit a national leader in health equity research to further enhance and advance the mission of the Health Equity Institute. These resources will allow you to further solidify UB's role as a leader in the promotion of health equity across our community and build upon existing partnerships with community leaders and clinical partners to promote health equity in research and clinical care. We envision this recruit will be an integral member of your team working with the NIMHD Center of Excellence.

UB recently launched the Advancing Top 25: Faculty Hiring initiative, though which the university plans to hire upward of 200 full-time faculty across the university over the next two years. To support faculty research, we also plan to expand our research administration support by hiring approximately 40 new professionals. Your work on health equity will be fully supported and enhanced by these efforts. In addition, enhancing faculty, staff and student diversity at UB is a top university priority, and we welcome and support your initiatives in the proposal to help diversify our faculty with these new recruitments. Strengths build on each other and, with the support of NIMHD, we hope to work even more diligently to make Buffalo a model for what can be achieved in health equity. The diversity of our region and our university community is something we celebrate and prioritize, as part of our core values and the commitment we have to our community.

As part of our commitment to the UB Community Health Equity Research Institute, the university has been supporting a full-time research administrator since its launch in 2019. We will continue supporting this salary and envision this administrator will be active in supporting the activities of the NIMHD Center of Excellence. We also support the 50% cost share of all faculty engaged in this proposal.

In closing, you have the full endorsement of our offices and that of the university in pursuit of these critical research resources for our community. As a scholarly community grounded in values of social justice, we are committed to cultivating a diverse, equitable and welcoming academic environment for the betterment of our region. We recognize that UB thrives because of our diversity. It is this diversity — of perspective, backgrounds, cultures and lived experiences — that contributes to UB's dynamic and intellectually stimulating environment. It enriches our research, our scholarly pursuits, our academic discourse — indeed, all that we endeavor to accomplish. Thank you for your continued work and commitment to our core values and mission.

Sincerely,

Satish K. Tripathi
President

A. Scott Weber
Provost and Executive Vice President for Academic Affairs

501 Capen Hall, Buffalo, NY 14260-1600
716.645.2901 (F) 716.645.3728
www.buffalo.edu

Jacobs School of Medicine and Biomedical Sciences
University at Buffalo

Office of the Vice President for Health Sciences and Dean

July 14, 2023

Timothy F. Murphy MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York

Dear Dr. Murphy,

As dean of the University at Buffalo (UB) Jacobs School of Medicine and Biomedical Sciences, as well as in my role as vice president for the UB's Health Science Schools, I write to fully support pursuit of your proposal, *Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers,* to the National Institute on Minority Health and Health Disparities (NIHMD).
I am in a unique role on campus to oversee six university schools including the School of Nursing; the School of Pharmacy and Pharmaceutical Sciences; the School of Public Health and Health Professions; the School of Social Work; the School of Dental Medicine; and of course, the medical school. From this vantage in reviewing the proposal you are preparing, I commend you for bringing together an interdisciplinary team, reflective of the numerous disciplines which can be strong resources for these efforts. UB is uniquely poised to have this full complement of strengths.

I recognize this center brings together a team you have built both within the university and across our community over the years to address the critical topic of health equity not only in research, but also specifically how it impacts the community we are part of. Our region is proud of and thankful for the work your group has accomplished to date in these regards, especially as your efforts in working with the community turned around the impact of COVID-19 on the black community. Additional support from NIHMD for a Center of Excellence, "Igniting Hope in Buffalo New York Communities: Training the Generation of Health Equity Researchers", you are proposing will only propel your team further.

From an administrative perspective, I am pleased to be part of the recruiting for and hiring of a newly created Carl Granger Endowed Chair in Health Equity who will assume the position of Director of the UB Community Health Equity Research Institute. With the support of Provost Weber, this investment will permit us the ability to recruit a national leader in health equity scholarship with hopes to further enhance the foundation you have set and further advance the university investment and commitment to achieving health equity in our community. As you know, since coming to UB a year and a half ago, I am fully committed to ensuring we are the best resource for our region on health equity as there is so much work to be done. We have a beautiful, highly diverse community that we always strive to be the best partner with, and this work is critical to that.

Following the designation of UB as a flagship institution in the SUNY system, UB has embarked on an extensive faculty hiring initiative. Many of these new hires will be in the health sciences schools. A

955 Main Street, Room 6190, Buffalo, NY 14203-1121
716.829.3355 (F) 716.829.2179 www.medicine.buffalo.edu

goal of this initiative is to increase the diversity of our faculty. Your proposal includes innovative approaches to contribute to this effort. To this end, we will actively include faculty who have effort on the NIMHD Center grant on search committees and in meeting with faculty candidates. In addition, we will work with your group to engage candidates of color with community partners to meet with candidates and show the candidates the Buffalo community from their important perspective. This approach has been quite effective in previous recruits.

Lastly, this center has significant resources committed to growing the next generation of leaders in health equity research. I have witnessed your success in a similar regard as PI of the UB Clinical and Translational Science Award in the talented, early career PIs you have fostered and mentored and as PI of the T35 training grant "Training the Next Generation of Clinician Scientists" and the influence it has on medical and pharmacy students. I am optimistic to see a similar model in finding and growing the future leaders in health equity and I have complete trust in your abilities to do so with your group. Health equity and all the challenges we face in Buffalo related to social determinants of health, make our community in critical need of support from NIMHD and position us to leverage that support toward meaningful progress. I thank you for continuing to pursue these opportunities that allow our expertise to grow to the betterment of our neighbors and beyond.

Best regards,



Allison Brashear, M.D., M.B.A.
Vice President for Health Sciences
Dean, Jacobs School of Medicine and Biomedical Sciences

Buffalo Center for Health Equity

July 17, 2023

Pastor George F. Nicholas
Buffalo Center for Health Equity
257 W. Genesee St., Suite 160
Buffalo, NY 14202

Dear Dr. Murphy,

I write this letter in full support of the proposal, Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers, to the National Institute on Minority Health and Health Disparities (NIMHD). As a community partner who has worked with you for years to the betterment of research and health equity in our region, I am hopeful NIMHD will recognize the value of our collaboration and the impact this support can have in continuing to close the health equity gaps in our community and beyond.

As you are aware, the African American Health Equity Task Force (AAHETF) was established to eliminate race-based health disparities among communities of color in the Greater Buffalo Region. This task force (a group comprised of local pastors, university faculty, community leaders and residents) formed for the specific purpose of changing public policy that impacts health outcomes with representation from all facets of our community with the university included. We came together to provide insight into the most pressing issues facing African Americans in the Greater Buffalo Region; to shed light on the fact that African Americans suffer disproportionately from a cluster of co-existing health problems that contribute to the onset of serious chronic life limiting illnesses and are aware that interventions vary greatly from that of other populations. Specifically, African American men, women, and children who reside in five ZIP codes within the City of Buffalo experience many of the worst health outcomes in Erie County. They are more likely to have serious, chronic, and often preventable diseases, and they have a rate of premature mortality that is almost 300% higher than Whites who live outside of these areas.

In my role as CEO for the Buffalo Center for Health Equity (BCHE), I fully appreciate the partnerships we have established and seen flourish in advancing health equity across our community. The BCHE was established in 2019 to address the challenges experienced by Black and/or financially distressed communities on the East Side of Buffalo, New York as a continuation of the work spearheaded by the AAHETF. The BCHE serves as a mechanism to create equity in health outcomes, that are influenced by the conditions into which people are born, and in which they develop, live, work, and worship. Upon our founding we have moved quickly and effectively on numerous community issues including the response to the global pandemic which was disproportionately affecting the neighborhoods we serve. Our success in turning those circumstances around is in part due to the productive collaborations we have with

your Community Health Equity Research Institute at UB; the UB Clinical and Translational Sciences Institute; and the Erie County Department of Health- Health Equity Office. It is fitting that these same partnerships bring us together to apply for this potential award, which is sorely needed in Buffalo.

I believe that the award we are applying for fits an essential need in our community. Training the next generation of health disparities researchers is a critical element in the work we are currently doing as it not only brings fresh ideas and perspectives, but protects the future of the strides we have already made. We, as a team, are in a unique position to engage and support future leaders in this area. We can help them as they grow and their infusion of talents I am confident will help us be more impactful. We are committed to working with you in partnership to give them the best training possible.

Lastly, you have my full support and that of the Buffalo Center for Health Equity with the recruitment of UB's new faculty. We recognize the impact the university has across our community and we very much want to be part of the conversation and planning for recruiting people from diverse backgrounds that mirror the beautiful tapestry of the community in Buffalo.

I am hopeful for a successful outcome.

Best,

Pastor George F. Nicholas
CEO, Buffalo Center for Health Equity

Erie County Department of Health
Public Health
Prevent. Promote. Protect.
GALE R. BURSTEIN, MD, MPH, FAAP
COMMISSIONER OF HEALTH

July 18, 2023

Timothy F. Murphy, MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Senior Associate Dean for Clinical and Translational Research
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York

Dear Tim,

On behalf of the Erie County Office of Health Equity, I am pleased to write this letter of support for your grant application, *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers,* to the National Institute on Minority Health and Health Disparities (NIMHD).

The Erie County Office of Health Equity (ECOHE), a division of the Erie County Department of Health, is committed to the work that you describe in the proposal, which we have discussed and planned together. Established by the Erie County Health Equity Act of 2021, the vision of the ECOHE is for all disadvantaged, marginalized, and diverse populations in Erie County, who presently experience higher rates of poor health outcomes, to achieve maximum health and wellness. The ECOHE's mission is to evaluate a wide variety of specific health outcomes among diverse populations to fully understand the depth of health disparities in Erie County and to partner with community members, healthcare providers, faith and philanthropic leaders, and organizations to enact programs that help disadvantaged, marginalized, and diverse populations in Erie County achieve maximum health and wellness. The partnership among my office, your Community Health Equity Research Institute, and the Buffalo Center for Health Equity led by Pastor Nicholas has been a most valuable and active partnership for all of us. My office and our partnership are committed to combatting the injustices that we see daily and work toward achieving health equity in our community.

The opportunity for my team to engage with and help train the next generation of health equity professionals through *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers* aligns closely with the work of our office. We anticipate that the research projects undertaken by this group of future leaders and trainees will inform our efforts by providing new data to drive effective policy. You and this up-and-coming group have the full support of my office and that of Erie County via our commitment to collaborate and contribute our own unique expertise.

Erie County Department of Health
Public Health
Prevent. Promote. Protect.
GALE R. BURSTEIN, MD, MPH, FAAP
COMMISSIONER OF HEALTH

An exciting direction of this proposal is its emphasis on translating the results of research into real world initiatives and policy changes so that the community benefits from the research. Our office, which has extensive reach throughout Buffalo and Erie County, will help guide early career researchers on their projects to help inform approaches that address key problems in the community. We are enthusiastic to continue to work together. Having an NIMHD Center of Excellence to attract new investigators into minority health and health disparities research will raise our work to new heights.

It is our hope that the NIMHD and its experts recognize our past successful collaborations with you, our commitment to this partnership, and perhaps most importantly, the impact they can have on our community via this award. You have our full support and our best wishes for a successful proposal.

Sincerely,

Kelly Marie Wofford
Director, Health Equity
Erie County Department of Health

95 Franklin Street • Buffalo, New York • 14202
Telephone: (716) 858-7690 • Fax (716) 858-8701 • Erie.Gov/Health

CAI
Change and Inspiration

TELEPHONE 212.594.7741 · FAX 212.629.3321
ADDRESS 505 Eighth Ave., Suite 1900, NY, NY 10018
WEBSITE www.caiglobal.org

July 27, 2023

Timothy F. Murphy MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York

Dear Dr. Murphy,

Cicatelli Associates Inc. (CAI), is pleased to enthusiastically support the grant application being submitted by the University of Buffalo to the National Institute of Minority Health and Health Disparities entitled "Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers."

CAI is a current recipient of the Centers for Disease Control and Prevention's (CDC) Racial and Ethnic Approaches to Community Health (REACH) grant in Buffalo, New York. In that capacity we currently partner with the Buffalo Center for Health Equity and the UB Community Health Equity Research Institute to inform and implement select program strategies.

CAI's REACH project is one of 31 REACH communities funded by CDC to identify and implement innovative and evidence-based strategies to reduce racial and ethnic health disparities in chronic disease. As part of this initiative CAI engages, mobilizes and builds the capacity of residents and stakeholders along the Ferry Street Corridor on Buffalo's East Side to partner to design and conduct needs assessment, utilize needs assessment data to identify drivers of enduring disparities, co-design solutions to address identified drivers, and in collecting and using data to assess impact and continuously improve.

The NIMHD Center of Excellence and REACH initiative have a common interest to eliminate health inequities in African American communities in Buffalo. Should you be successful in securing NIH funding, we look forward to exploring how CAI might partner to support achievement of project objectives, including the potential to participate on the Community Engagement and Dissemination Core of the NIMHD Center of Excellence.

Our work together has great potential in improving health outcomes for our community.

Sincerely,

Barbara Cicatelli
President and Founder

COUNTY OF ERIE

MARK C. POLONCARZ
COUNTY EXECUTIVE

July 12, 2023

Tim Murphy, MD
875 Ellicott St.
Room 6091
Buffalo, New York 14203

Re: Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers Proposal

Dear Dr. Murphy,

As County Executive of Erie County, which is home to Buffalo, New York as well as the University at Buffalo (UB), I fully support your proposal, *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers,* to the National Institute on Minority Health and Health Disparities (NIHMD).

I have always been pleased to work with the University at Buffalo as it takes an active role in the WNY region - from volunteering beyond the campus, to using the time and talent of UB scholars to focus on issues affecting our neighbors. With a community-centered approach at the forefront of its mission, your Community Health Equity Research Institute, established in 2019 in close partnership with the UB African American Health Equity Task Force has become a regional asset. Your mission to perform research that advances understanding of the root causes of health inequities; and develop innovative solutions to eliminate health inequities in our region, with a focus on those experienced by African Americans is critical to the efforts we need to make as a community to improve health outcomes for everyone.

As you know, Erie County, and particularly the City of Buffalo, suffer from disturbing race and income-based health disparities. In Buffalo, 30% of residents live below the poverty level, and the average life expectancy of a black person is 12 years less than a white person. Not surprisingly, the coronavirus pandemic heightened these longstanding inequities in the region, yet our work together, including your team in collaboration with community leaders and our governmental offices, turned around the disproportionate fatalities in people of color and became a beacon of hope for others metropolitan areas.

In 2021, I worked with the Erie County Legislature to create the Erie County Department of Health Office of Health Equity. Its vision is for all disadvantaged, marginalized, and diverse populations in Erie County, who presently experience higher rates of poor health outcomes, to achieve maximum health and wellness. I appointed Kelly Wofford, a member of the African American Health Equity Task Force to lead the office. The partnership among this office, the community-based Buffalo Center for Health Equity and your UB Community Health Equity Research Institute has unlimited potential in moving the needle on health disparities in our region.

Our needs in Erie County are vast. In the City of Buffalo, 30% of families live in poverty with over 63% of families having women as head of household. Each year, approximately 1,000 children are born to mothers without a high school diploma and 25% of women do not receive prenatal care. The City of Buffalo's population is 37 % Black or African American; 14% Hispanic; 1 % Native American making Buffalo a minority-majority city. We have much work to do together and my office is committed to working with you and your team. The goal of your proposed NIMHD Specialized Center of Excellence in Investigator Development and Community Engagement fits with the needs of our community to increase our efforts in the fight to eliminate health disparities in Buffalo and Erie County.

I am hopeful this award comes to fruition as it could help further the work being done on health equity across our region and beyond. Best wishes for a successful proposal.

Sincerely yours,

Mark C. Poloncarz
Erie County Executive

THE SENATE
STATE OF NEW YORK

CHAIRMAN
TRANSPORTATION
SELECT COMMITTEE ON
STATE-NATIVE AMERICAN RELATIONS

COMMITTEES
BANKS
CITIES 2
ENERGY AND TELECOMMUNICATIONS
FINANCE
INSURANCE
RULES

TIMOTHY M. KENNEDY
SENATOR, 63RD DISTRICT

ALBANY OFFICE:
ROOM 708
LEGISLATIVE OFFICE BUILDING
ALBANY, NEW YORK 12247
(518) 455-2426 OFFICE
(518) 426-6851 FAX

DISTRICT OFFICE:
37 FRANKLIN ST., SUITE 550
BUFFALO, NEW YORK 14202
(716) 826-2683 OFFICE
(716) 826-2793 FAX

E-MAIL ADDRESS:
KENNEDY@NYSENATE.GOV

July 26, 2023

Timothy F. Murphy MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York

Dear Dr. Murphy,

I fully support your application to the National Institute on Minority Health and Health Disparities (NIMHD), Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers.

As a New York State Senator, I have seen firsthand the challenges New Yorkers face, yet I see even more vividly the many things we are challenged by and strive to overcome as Buffalonians. One of our community's top priorities is achieving health equity. It is unacceptable that neighbors, living in certain parts of our community, or coming from diverse backgrounds, live on average ten years less than their neighbors. I commend you for your work on this important initiative.

As you know, I joined you and a group of community leaders from the African American Health Equity Task Force in the pivotal meeting with UB President Satish Tripathi and the UB Provost in 2019 that led to the formation of the UB Community Health Equity Research Institute. My office has worked with and supported your groups from the outset. Zeneta Everhart, who serves as Director of Diversity & Inclusion in my office, is an active member of the African American Health Equity Task Force. My office is enthusiastic in working with you as you launch and implement an NIMHD Center of Excellence in Investigator Development and Community Engagement.

You and your team of faculty and community partners have aligned your work in the UB Community Health Equity Research Institute to be responsive to the needs of our community, particularly those who experience profound disparities in health outcomes due to adverse social determinants of health. I am an advocate for the work of UB and your team, and will continue to champion the needs of our under-resourced and under-served communities. You have given voice to many and it is my hope that with this training opportunity being offered in our wonderful community, you and our regional leadership can continue to combat inequality in health. Training the next generation of health equity researchers under the leadership of your group is ideal. You have done excellent work and we need more scholars in our community tackling these problems in a holistic, interdisciplinary way.

I firmly believe that by investing in research pursuits on health equity in Buffalo, we will attract talent to benefit from your mentorship, and advance the health equity field. Most importantly, I believe it will improve the lives of many in Buffalo and the region. Thank you for your commitment and leadership in this effort.

Sincerely,

Timothy M. Kennedy
New York State Senator, 63rd District

CITY OF BUFFALO
OFFICE OF THE MAYOR

BYRON W. BROWN
MAYOR

July 21, 2023

Timothy F. Murphy, MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York

Dear Dr. Murphy,

It is with pleasure that I write this letter of support for your application to the National Institute on Minority Health and Health Disparities (NIMHD), *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers*. I recognize the value of this work and proposal for our community and am thankful to see the University at Buffalo and your Community Health Equity Research Institute working to bring more resources to our region to combat the health inequities our neighbors face.

Buffalo, NY has such strengths and sadly has faced significant challenges. We have a community which is beautifully diverse in countless ways, which horrifically, made us the target of a racially motivated shooting in May 2022. That event highlighted for the entire nation the challenges our community faces. However, I believe it also demonstrated the strength of our bonds across our neighborhoods and how we can persevere when we work in partnership. This work is most effective when all voices are heard and given agency. You have representation from critical voices in relation to health equity and have engaged leadership from government, community organizations, and academic leadership.

The proposal that you are submitting to NIMHD has the potential to create even greater opportunities for a community that needs every tool and investment it can access to improve lives and circumstances for so many, with more positive health outcomes being essential.

Thank you for your past work and your commitment to Buffalo via your Igniting Hope efforts.

Sincerely,

Byron W. Brown

Byron W. Brown
Mayor

ROOM 201 CITY HALL / BUFFALO, NY 14202 / (716) 851-4841 / FAX (716) 851-4860 / www.city-buffalo.com

BRIAN HIGGINS
26TH DISTRICT, NEW YORK

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON TRADE
SUBCOMMITTEE ON SOCIAL SECURITY

COMMITTEE ON THE BUDGET

ASSISTANT WHIP

Congress of the United States
House of Representatives
Washington, DC 20515–3226

2459 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3306
(202) 226-0347 (FAX)

726 EXCHANGE STREET
SUITE 601
BUFFALO, NY 14210
(716) 852-3501
(716) 852-3929 (FAX)

800 MAIN STREET
SUITE 3C
NIAGARA FALLS, NY 14301
(716) 282-1274
(716) 282-2479 (FAX)

higgins.house.gov

July 26, 2023

Timothy F. Murphy MD
SUNY Distinguished Professor
Director, UB Clinical and Translational Science Institute
Director, UB Community Health Equity Research Institute
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo, State University of New York
Buffalo, New York 14260

Re: SUNY University at Buffalo's grant request to the National Institute on Minority Health and Health Disparities (NIMHD)

Dear Dr. Murphy:

It has been conveyed to me that the University's Community Health Equity Research Institute is pursuing a health equity center grant with the National Institute on Minority Health and Health Disparities (NIMHD) titled *Igniting Hope in Buffalo New York Communities: Training the Next Generation of Health Equity Researchers*. I am pleased to convey my support for this submission.

Research has repeatedly shown vast, imbalanced health outcomes throughout the U.S. that are frequently correlated to race and socioeconomics. Unfortunately, Buffalo and Western New York experience profound race-based health inequities, particularly in predominantly African American neighborhoods of the East Side of Buffalo. We had an excellent discussion about these issues, and about your Community Health Equity Research Institute, when you visited my office in Washington, along with Pastor Kinzer Pointer and Dr. Eliseo Pérez-Stable, Director of NIMHD in March 2020, days before workplaces and schools shut down as a result of the pandemic. It is most encouraging to me that your work has progressed to position you to submit this outstanding proposal to train a new generation of health equity researchers.

Again, I commend you for your important work in this area and am pleased to commend your application to the National Institute on Minority Health and Health Disparities. Thank you very much,

Sincerely,

Brian Higgins
Member of Congress

NIH Generated message:

The Other Plan(s) attachment included with the application is not evaluated during the peer review process but will be evaluated prior to a funding decision. Although part of the official submission, the attachment is maintained as a separate document in eRA Commons viewable by authorized users and is not part of this assembled application.

OMB Number: 4040-0001
Expiration Date: 11/30/2025

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **UEI*:** LMCJKRFW5R81

Legal Name*: The Research Foundation for SUNY on behalf of U. at Buffalo
Department: Sponsored Projects Services
Division:
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Amy		Lagowski	

Position/Title: Agreement Administartor
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567
Phone Number*: 716-645-4419 Fax Number: Email: amy.lagowski@buffalo.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): Private, Non-profit

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers

12. PROPOSED PROJECT

Start Date*	Ending Date*
04/01/2024	03/31/2029

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Research Foundation for SUNY on behalf of U. at Buffalo
UEI:	LMCJKRFW5R81
Street1*:	The UB Commons
Street2:	520 Lee Entrance, Suite 211
City*:	Amherst
County:	Erie
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14228-2567
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB Clinical and Translational Research Center
UEI:	
Street1*:	875 Ellicott Street
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14203-1034
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Jacobs School of Medicine and Biomedical Sciences
UEI:
Street1*: 955 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1034
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Public Health and Health Professions
UEI:
Street1*: 3435 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3099
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 4

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Nursing
UEI:
Street1*: 3435 Main Street- Wende Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3010
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 5

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Architecture and Planning
UEI:
Street1*: 3435 Main Street- Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3015
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 6

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Community Health Equity Research Institute
UEI:
Street1*: 875 Ellicott Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1070
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 7

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Buffalo Center for Health Equity
UEI:
Street1*: 257 West Genesee Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14202-2657
Project/Performance Site Congressional District*: NY-026

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ○ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ○ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Abstract_Admin_Core.pdf
8. Project Narrative*	
9. Bibliography & References Cited	Bibliography-_Administrative_Core.pdf
10.Facilities & Other Resources	
11.Equipment	

Tracking Number: GRANT13951079
Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

The organizational and governance structure of our NIMHD Center of Excellence in Investigator Development and Community Engagement (Center of Excellence) is guided by its mission, which is to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community. The Center of Excellence will be embedded in the UB Community Health Equity Research Institute (Health Equity Institute), a fully sanctioned university-wide institute founded in 2019 as a direct result of our partnership and collaborations with community leaders and community members. The Health Equity Institute includes faculty from all 12 schools of the University at Buffalo, providing an immediate connection with researchers and mentors in essentially all disciplines that bring expertise to perform innovative research to address the many social determinants of health. Estimates are that improving healthcare will reduce disparities in health outcomes by 10 to 20%. It is critical that research addresses the upstream factors that account for these disparities. Another noteworthy feature of our administrative structure is the integration of community leaders as part of the leadership teams of the Center of Excellence and of each Core, leveraging our influential and far-reaching community-university-government partnership. The Administrative Core will coordinate and manage Center of Excellence activities with a responsive governance and inclusive approach, engaging community participation in the leadership and the work of the Center (Aim 1). The leadership of the Administrative Core will organize and integrate core initiatives to ensure communication and synergy among cores, while providing expertise and support for maintaining compliance with policies and procedures (Aim 2). With the African American Health Equity Task Force serving as an “umbrella” group of our community-university-government partnership, the well-attended monthly Task Force meetings are highly effective in ensuring continuous communication and coordination between the Center of Excellence and the community. We will carefully monitor progress toward milestones through evaluation and continuous quality improvement, while tracking key milestones for processes, productivity, and impact of the work of the Center of Excellence (Aim 3). We will track scholarly outcomes and career trajectory of early-career investigators supported by pilot studies. Our vision is the Center of Excellence will provide training, individualized mentoring, and professional development to early-stage investigators to substantially increase the number of investigators and leaders in health disparities research. Thus, our Center of Excellence will have enormous impact in our environment to address root causes of health inequities and lead to sustainable system-level changes in race-based health inequities in Buffalo and nationally through sharing the innovative interventions that our investigators develop and test.

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Timothy Middle Name Last Name*: Murphy Suffix: M.D.

Position/Title*: SUNY Distinguished Professor
Organization Name*: STATE UNIVERSITY OF NEW YORK AT BUFFALO
Department: Medicine
Division:
Street1*: 875 Ellicott St.
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1034

Phone Number*: (716) 881-8911 Fax Number:

E-Mail*: murphyt@buffalo.edu

Credential, e.g., agency login: tmurphy

Project Role*: Other (Specify) Other Project Role Category: Admin Core Director

Degree Type: MD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Carol Middle Name Last Name*: Van Zile Tamsen Suffix: Ph.D

Position/Title*: Director
Organization Name*: SUNY at Buffalo
Department: Office of Curriculum, Assessment and Teaching Transformation (CATT)
Division:
Street1*: 5A Norton Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14260-1800

Phone Number*: (716) 645-3905 Fax Number:

E-Mail*: cmv3@buffalo.edu

Credential, e.g., agency login: CAROLVAN

Project Role*: Other (Specify) Other Project Role Category: Evaluator

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Timothy		Murphy	M.D.	Principal Investigator	190,890.00	1.0			8,838.00	5,784.00	14,622.00
2.		Carol		Van Zile Tamsen	Ph.D	Evaluator	142,147.00	0.6			3,554.00	2,326.00	5,880.00
3.		TBN		Program Manager		Program Manager	65,000.00	6.0			32,500.00	13,325.00	45,825.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **66,327.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**66,327.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Case 1:25-cv-10814-WGY Document 12-24 Filed 04/04/25 Page 171 of 375

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	18,667.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and Sharing Costs	0.00
Total Other Direct Costs	**18,667.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**86,494.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	86,494.00	52,761.00
		Total Indirect Costs	**52,761.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**139,255.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	139,255.00

L. Budget Justification*	File Name: Budget_Justification-Admin_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Timothy		Murphy	M.D.	Principal Investigator	194,708.00	1.0			8,838.00	5,907.00	14,745.00
2.		Carol		Van Zile Tamsen	Ph.D	Evaluator	144,909.00	0.6			3,554.00	2,375.00	5,929.00
3.		TBN		Project Manager		Program Manager	66,300.00	6.0			33,150.00	13,757.00	46,907.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **67,581.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**67,581.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	18,667.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and Sharing Costs	0.00
Total Other Direct Costs	**18,667.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**87,748.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	87,748.00	53,526.00
		Total Indirect Costs	**53,526.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**141,274.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	141,274.00

L. Budget Justification*	File Name: Budget_Justification-Admin_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Timothy		Murphy	M.D.	Principal Investigator	198,602.00	1.0			8,838.00	6,035.00	14,873.00
2.		Carol		Van Zile Tamsen	Ph.D	Evaluator	147,889.00	0.6			3,554.00	2,427.00	5,981.00
3.		TBN		Program Manager		Program Manager	67,626.00	6.0			33,813.00	14,540.00	48,353.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **69,207.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**69,207.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	18,667.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and Sharing Costs	0.00
Total Other Direct Costs	**18,667.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**89,374.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	89,374.00	54,518.00
		Total Indirect Costs	**54,518.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**143,892.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	143,892.00

L. Budget Justification*	File Name: Budget_Justification-Admin_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Timothy		Murphy	M.D.	Principal Investigator	198,602.00	1.0			8,838.00	6,035.00	14,873.00
2.		Carol		Van Zile Tamsen	Ph.D	Evaluator	147,889.00	0.6			3,554.00	2,427.00	5,981.00
3.		TBN		Program Manager		Program Manager	68,979.00	6.0			34,489.00	14,830.00	49,319.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **70,173.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**70,173.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		Funds Requested ($)*
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	18,667.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and sharing Costs	0.00
Total Other Direct Costs	**18,667.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**90,340.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	90,340.00	55,107.00
		Total Indirect Costs	**55,107.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**145,447.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	145,447.00

L. Budget Justification*	File Name: Budget_Justification-Admin_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Timothy		Murphy	M.D.	Principal Investigator	198,602.00	1.0			8,838.00	6,035.00	14,873.00
2.		Carol		Van Zile Tamsen	Ph.D	Evaluator	147,889.00	0.6			3,554.00	2,427.00	5,981.00
3.		TBN		Program Manager		Program Manager	70,358.00	6.0			35,179.00	15,127.00	50,306.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **71,160.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**71,160.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	1,500.00
2. Foreign Travel Costs	
Total Travel Cost	**1,500.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	18,667.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Data Management and Sharing Costs	0.00
Total Other Direct Costs	**18,667.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**91,327.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	91,327.00	55,709.00
		Total Indirect Costs	**55,709.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**147,036.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	147,036.00

L. Budget Justification*	File Name: Budget_Justification-Admin_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Budget Justification: Administrative Core

A. Personnel Salaries and Wages

Senior/Key Personnel

Timothy Murphy, MD

- Principal Investigator, NIMHD Center of Excellence in Investigator Development and Community Engagement
- Effort: 1.0 calendar months (Institutional support years 1-5: 0.50 calendar months)

Dr. Murphy is a SUNY Distinguished Professor, Founding Director of the Community Health Equity Research Institute and Director of the Clinical and Translational Science Institute in the Jacobs School of Medicine and Biomedical Sciences, University at Buffalo. He is an accomplished physician scientist who has been continuously funded by the NIH as a PI of R01 grants since 1983. His work involves T1 translational research on pathogenesis and vaccine development for respiratory tract bacterial pathogens. He has extensive experience as a mentor and is PI of a T35 training grant “Training the next generation of clinician scientists.”

Responsibilities:

- Oversee the strategic planning and direction of the Center of Excellence
- Guide the overall activities of the Center of Excellence
- Chair the Leadership Team
- Responsible for assuring compliance with applicable federal regulations and NIH policies
- Manage the budget
- Oversee the DEIA Action Plan

Pastor George Nicholas, MDiv

- Co-Director, Administrative Core
- Effort: Independent Contractor

Pastor Nicholas is Senior Pastor of Lincoln Memorial United Methodist in Buffalo, NY. He has been recognized by the General Board of Global Ministries of the United Methodist for his work on urban ministries. Pastor Nicholas is an advocate for social justice and community revitalization. A founding member of the Concerned Clergy Coalition of Western New York, he is the convener of the African American Health Equity Task Force and CEO of the Buffalo Center for Health Equity (501(c)3). He is an influential and visionary community leader.

Responsibilities

- Work with the Director to:
    - Oversee the strategic planning and direction of the Center of Excellence
    - Guide the overall activities of the Center of Excellence
    - Manage the budget
- Serve on Leadership Team
- Connect Buffalo Center for Health Equity with Center of Excellence initiatives
- Facilitate active involvement of community leaders and community members

Carol Van Zile Tamsen, PhD

- Evaluator
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Van Zile-Tamsen is Associate Vice Provost and Director Office of Curriculum, Assessment and Teaching Transformation Dr. Van Zile-Tamsen leads the university efforts to achieve programmatic and instructional excellence and increased student learning and success. She is a nationally recognized expert in evaluation and assessment of educational and training programs.

Responsibilities

- Oversee and implement evaluation and continuous quality improvement of the project
- Communicate progress and evaluation data to Center of Excellence Leadership
- Serve on the Center of Excellence Steering Committee

Oscar Gomez, MD, PhD

- Director, Investigator Development Core
- Center of Excellence Leadership Team
- Effort as needed

Dr. Gomez is an Associate Professor of Pediatrics, School of Medicine and an active advocate of recruiting underrepresented minorities in medical science to training programs. He is a member of the Harold Amos Medical Faculty Development Program of The Robert Wood Johnson Foundation, first as a scholar beginning 2009, and later as an alumnus beginning in 2012. This program is dedicated to career development of underrepresented minorities in medical science in the US. He is co-investigator and associate lead of the CTSI-associated KL2-mentored research award program in which he serves as a faculty advisor for early-career scholars. He conducts studies on the epidemiology of childhood diarrhea among children in low- and middle-income countries in Latin America and studies on hepatitis C- exposure and infection among infants in Buffalo, a condition that disproportionately impacts communities that experience adverse social determinants of health.

Responsibilities:

- Lead the Investigator Development Core
- Collaborate with Administrative Core in managing pilot project award announcements
- Coordinate training and mentoring activities
- Serve on Center of Excellence Leadership Team

Robert Silverman, PhD

- Director, Community Engagement and Dissemination Core
- Center of Excellence Leadership Team
- Effort as needed

Dr. Silverman is Professor of Urban and Regional Planning in the School of Architecture and Planning He is an internationally regarded urban planning scholar whose work focuses on community development, inequity in urban communities, affordable housing, and education policy. He has worked closely with Buffalo East Side Communities since he joined the UB faculty in 2003.

Responsibilities

- Lead the Community Engagement and Dissemination Core
- Facilitate linking of pilot studies awardees with community partners
- Work with Buffalo Center for Health Equity on dissemination of research results to community
- Work with Administrative Core in reviewing and managing the Community Partnership grants

Pastor Kinzer Pointer, MM

- Co-Director, Investigator Development Core
- Center of Excellence Steering Committee
- Effort: Independent Contractor

Pastor Pointer is the pastor of Liberty Missionary Baptist Church, President and CEO of Greater Buffalo United Ministries and Chair, Erie County Poverty Committee. He is a mentor in the National Medical Association and has worked for the past five years with Drs. Murphy and Gomez on the T35 training grant “Training the Next Generation of Clinician Scientists.” He co-teaches a course in the medical school with Dr. Henry Taylor, “Health in the Neighborhood,” in which students review key literature and meet with and work with community members in their neighborhoods. Pastor Pointer also serves on the Board of the Community Health Equity Research Institute.

Responsibilities
- Co-Director of Investigator Development Core (IDC)
- Provide guidance and contribution to IDC
- Provide mentorship to pilot study awardees
- Serve on Center of Excellence Steering Committee

Rita Hubbard Robinson, JD
- Center of Excellence Steering Committee
- Effort: Independent Contractor

Rita Hubbard Robinson is the founder and Chief Executive Officer of NeuWater & Associates, LLC, a company focused on improving population health through projects that focus on improving access to healthy food, employment, industry development, youth development, entrepreneurial development, health and wellness initiatives, and green community redevelopment. As an influential leader she has been committed to the improvement of health and social determinants of health for over 30 years. Ms. Hubbard-Robinson works with several community-based teams to improve access to healthy produce in Buffalo neighborhoods that experience food insecurity. She is treasurer of the Buffalo Center for Health Equity, runs the First Fruits Food Pantry that serves 200 East Side families, and has won numerous awards for her work in the community.

Responsibilities
- Serve on Center of Excellence Steering Committee
- Provide a community perspective to the Center Excellence through the Steering Committee
- Connect Buffalo Center for Health Equity with Center of Excellence initiatives

Henry Taylor, PhD
- Center of Excellence Steering Committee
- Co-Investigator, Community Engagement and Dissemination Core
- Co-Investigator, Investigator Development Core
- Effort as needed

Dr. Taylor is Professor of Urban and Regional Planning, School of Architecture and Planning, Director of the Center for Urban Studies; and Associate Director, UB Community Health Equity Research Institute. His areas of expertise include urban development, housing, gentrification, underdeveloped neighborhoods, shrinking cities, race and class, and U.S.-Cuba relations. His research focuses on a historical and contemporary analysis of underdeveloped urban neighborhoods, social isolation, and race and class issues among people of color, especially African Americans and Latinos. Dr. Taylor designed and conducts the *Urban Internship Program,* which creates opportunities for graduate and undergraduate students to become involved in neighborhood redevelopment initiatives and research projects. He has trained numerous students in this program over the years. He is also the Co-leader of the CTSI Workshop series in Health Equity.

Responsibilities:
- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Provide guidance and contribution to the Investigator Development Core
- Serve on Center of Excellence Steering Committee
- Serve as Center of Excellence advocate to selected pilot studies awardees
- Facilitate partnerships and collaborations in the School of Architecture and Planning
- Help identify mentors for pilot studies awardees as needed

Heather Orom, PhD
- Center of Excellence Steering Committee
- Co-Investigator, Community Engagement and Dissemination Core
- Effort as needed

Dr. Orom is Associate Professor of Community Health and Health Behavior and Associate Dean for Equity, Diversity and Inclusion in the School of Public Health. Her research focuses on the causes of health disparities with a particular interest in how discrimination influences health outcomes. Dr. Orom has led many projects and has collaborated on many projects that have advanced understanding of health inequities. She engages in applied health equity research for local community organizations, assisting with evaluation and other research needs. Dr. Orom is an Associate Director of the Community Health Equity Research Institute

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships and collaborations in the School of Public Health and Health Professions
- Serve on Center of Excellence Steering Committee

Susan Grinslade, PhD, RN

- Center of Excellence Steering Committee
- Co-Investigator, Community Engagement and Dissemination Core
- Effort as needed

Dr. Grinslade is Clinical Professor in the School of Nursing and fellow in the American Academy of Nursing with expertise in public health nursing and a passion for health equity. She is also an Associate Director of the Community Health Equity Research Institute. She led the Million Hearts Initiative in Buffalo (a CDC program to reduce heart disease) facilitating a partnership between the School of Nursing and African American East Side communities. She has particular expertise in community based participatory research. Dr. Grinslade was an original member of the African American Health Equity Task Force and was instrumental in connecting UB faculty with the Task Force.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships and collaborations in the School of Nursing
- Provide guidance on community based participatory research
- Serve on Center of Excellence Steering Committee

Other Personnel

Project Manager

- To be named
- Effort: 6.0 Calendar Months

Responsibilities:

- Work with Center of Excellence leaders in implementing the many initiatives outlined in this proposal.
- Provide project management support for the solicitation and review of pilot studies letters of intent and full proposals
- Coordinate the quarterly meetings of the Community Advisory Board and the annual meetings of the External Advisory Committee
- Provide project management support for the Community Partnership grants
- Work with the Institute Administrator of the UB Community Health Equity Research Institute in organizing and coordinating the seminars, workshops and annual pilot studies symposium.

Other Direct Costs

Travel $1,500

PI Murphy will attend the annual NIMHD Centers of Excellence grantees meeting, held at or near NIH, Bethesda, MD. We have approximated expenses for travel from Buffalo, NY to MD.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		344,448.00
Section B, Other Personnel		0.00
Total Number Other Personnel	0	
Total Salary, Wages and Fringe Benefits (A+B)		344,448.00
Section C, Equipment		0.00
Section D, Travel		7,500.00
1. Domestic	7,500.00	
2. Foreign	0.00	
Section E, Participant/Trainee Support Costs		0.00
1. Tuition/Fees/Health Insurance	0.00	
2. Stipends	0.00	
3. Travel	0.00	
4. Subsistence	0.00	
5. Other	0.00	
6. Number of Participants/Trainees	0	
Section F, Other Direct Costs		93,335.00
1. Materials and Supplies	0.00	
2. Publication Costs	0.00	
3. Consultant Services	93,335.00	
4. ADP/Computer Services	0.00	
5. Subawards/Consortium/Contractual Costs	0.00	
6. Equipment or Facility Rental/User Fees	0.00	
7. Alterations and Renovations	0.00	
8. Other 1	0.00	
9. Other 2	0.00	
10. Other 3	0.00	
11. Other 4	0.00	
12. Other 5	0.00	
13. Other 6	0.00	
14. Other 7	0.00	
15. Other 8	0.00	
16. Other 9	0.00	
17. Other 10	0.00	
Section G, Direct Costs (A thru F)		445,283.00
Section H, Indirect Costs		271,621.00

Section I, Total Direct and Indirect Costs (G + H)	716,904.00
Section J, Fee	0.00
Section K, Total Direct and Fee (I + J)	716,904.00

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OMB Number: 0925-0001
Expiration Date: 01/31/2026

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 3C8 Research Plan

L MB Number: 9C25-9991
Expiration Date: 91/31/2926

Introduction

1. Introduction to Application
(for Resubmission and Revision applications)

Research Plan Section

2. Specific Aims	Aims_Admin_Oore.pdf
3. Research Strategy*	Admin_Oore_Research_Strategy.pdf
0. Progress Report Publication 4ist	

L ther Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI 4eadership Plan

8. Oonsortium/Oontractual Arrangements

C. 4etters of Support

19. Resource Sharing Plan(s)

11. L ther Plan(s)

12. Authentication of Key Biological and/or Ohemical Resources

Appendix

13. Appendix

B. Administrative Core: Organizational and Governance Structure

B1. Specific Aims

The mission of our NIMHD Center of Excellence in Investigator Development and Community Engagement (Center of Excellence) is to train and develop the next generation of health disparities investigators to perform innovative research in minority health and health disparities in partnership with our community and to the benefit of the community. The work will advance understanding of the root causes and develop and test innovative solutions to eliminate health inequities. Our vision is that these investigators will “move the needle” on health disparities so that wellness and social well-being become a reality for all people in Buffalo, including people of color who have serious, chronic, preventable diseases and higher mortality rates.

The Center of Excellence will be embedded in the UB Community Health Equity Research Institute (Health Equity Institute), providing an immediate connection with researchers in essentially all disciplines that bring expertise to perform innovative research to address the many social determinants of health (**Figure B1**). Estimates are that improving healthcare will reduce disparities in health outcomes by 10 to 20% (1-3). Thus, it is critical that research addresses the upstream factors that account for these disparities. Examples of important expertise include economics, urban planning, law and social justice, social services, education, big data analytics, epidemiology, health-related fields, policy development, basic sciences and more.



Figure B1. The Center of Excellence is embedded in the Community Health Equity Research Institute, facilitating seamless communication and partnerships with the community and each of the 12 schools of UB.

The Health Equity Institute has an Advisory Board that includes a leader from each of the 12 UB schools and several community leaders. The Dean of each UB school identified a representative, such as an Associate Dean or a faculty leader in health disparities research, to serve on the Board. This mechanism engages the entire university and important sectors of the community, providing an excellent resource for developing and maintaining relationships with community stakeholders and university expertise. We will include reports on the Center of Excellence to the Health Equity Institute Board to facilitate communication and collaboration.

Our Health Equity Institute also encompasses the UB Center for Urban Studies, which is a research, neighborhood planning and community development center focusing on the transformation of vulnerable, under-developed and marginalized neighborhoods into healthy communities controlled by its residents. The Center for Urban Studies is led by Dr. Henry Taylor, who is also an Associate Director of the Health Equity Institute and Co-I on this Center of Excellence.

The Administrative Core provides leadership and guides the overall vision of the Center of Excellence. Aims are:

Aim 1. Coordinate and manage Center of Excellence activities with a responsive governance and inclusive approach, engaging community participation in Center activities.

Aim 2. Organize and integrate core initiatives to ensure communication and synergy among cores, while providing expertise and support for maintaining compliance with policies and procedures.

Aim 3. Monitor progress toward milestones through evaluation and continuous quality improvement, while tracking key milestones for processes, productivity and impact of the work of the Center of Excellence.

B2. Significance and Environment

Partnering with the Health Equity Institute advances the mission of the Center of Excellence by leveraging the extensive reach of the Health Equity Institute. This administrative structure:

- strengthens communication throughout UB regarding the outstanding training and career development opportunity that the Center of Excellence brings to our environment
- facilitates communication to eligible faculty and postdocs to apply for pilot studies and work with us
- introduces early career faculty to mentors from multiple disciplines
- facilitates multidisciplinary collaborations
- enhances awareness of the research resources throughout the schools of the university
- links early career investigators with community partners and community collaborators.

B3. Innovation

- **Integrated Leadership.** The integrated leadership of the Administrative Core between community partners and the university leverages the nine-year partnership to which multiple stakeholders have made a continuing commitment. The Co-Director of the Center of Excellence, Pastor George Nicholas, is an influential community leader. The leadership team of each core includes community members.
- **Community-driven Research.** The research of the Health Equity Institute is community-driven. For example, the NIH-supported Igniting Hope conference series was conceived and has been conducted as a partnership with community co-investigators (4). This approach, guided by our shared values, will continue to be a theme of all our work and the work of the Center of Excellence.
- **Broadly Engaged Team Science** merges team science and community-engaged research (5). The Center of Excellence integrates multiple disciplines to nurture collaborations between researchers, community organizations, health service providers, public health agencies, and policymakers.
- **Addressing the Range of Social Determinants of Health (SDOH).** The participation of all 12 UB schools reflects our commitment to addressing the range of SDOH, including, for example, educational opportunity (School of Education), disinvested neighborhoods (School of Architecture and Planning), the criminal justice system (School of Law), etc.
- **Continuous Communication and Coordination.** With the African American Health Equity Task Force serving as an “umbrella” group, our well-attended monthly meetings are highly effective in ensuring continuous communication and coordination between the Center of Excellence and the community.

B4.1 Action Plan for Aim 1.

Aim 1. Coordinate and manage Center of Excellence activities with a responsive governance and inclusive approach, engaging community participation in Center activities.

The organizational and governance structure (**Figure B2**) is designed to have clear reporting lines, advisory groups representing key constituencies and expertise (gold boxes), integration and coordination of all components of the Center of Excellence and a reporting structure to the highest levels of university leadership, reflecting the value that the university places on this Center of Excellence and its goals.

Leadership. Center of Excellence leaders and participants have well-defined roles and responsibilities. The Leadership Team includes the Director, Co-Director, and the Core Directors. The Director and Co-Director oversee the strategic planning and direction of the Center of Excellence, guide its overall activities, and oversee the budget along with the Leadership Team.

Members of the **Leadership Team:**

- **Timothy Murphy MD, Director,** an accomplished physician scientist in the School of Medicine, serves as Director. As founding Director of the UB Clinical and Translational Science Institute (CTSI) and PI of the Clinical and Translational Science Award (CTSA), he established its vision in 2015 “to advance and accelerate research to reduce health disparities and improve the health of our community and the nation.” He has extensive experience as a mentor and is PI of a T35 training grant, *Training the Next Generation of Clinician Scientists* (T35 AI 089693), aligning with a major training focus of this Center of Excellence. In the first ten years of the T35 training grant, 37% of trainees are in NIH-designated groups that experience health disparities and 62% are women.

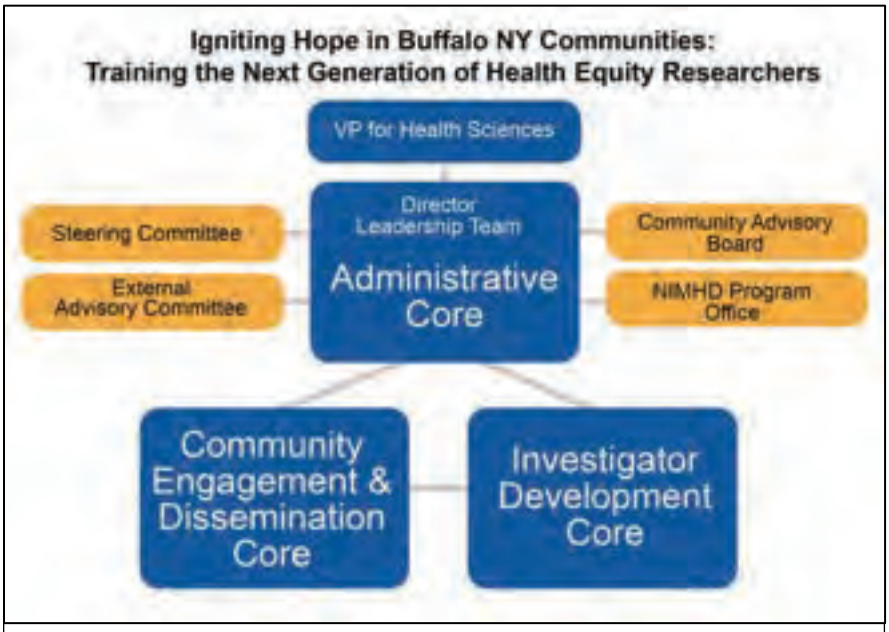


Figure B2. Governance structure of Center of Excellence

- **Pastor George Nicholas MDiv, Co-Director,** is an advocate for social justice and community revitalization. A founding member of the Concerned Clergy Coalition of Western New York, he is convener of the African American Health Equity Task Force and CEO of the Buffalo Center for Health Equity (501(c)3). He is an influential and visionary community leader.
- **Oscar Gomez MD PhD, Director, Investigator Development Core**, is a physician scientist with a longstanding commitment and experience in mentoring individuals underrepresented in health science. He is a member of the Harold Amos Medical Faculty Development program, which is dedicated to career development of people of color in medical science in the US. He was first a scholar in the program and is now a faculty advisor. He is a member of the UB Council on Inclusion in Medicine and Science Executive Committee and Associate Program Lead of the UB CTSA KL2 mentored career development program.
- **Robert Silverman PhD, Director, Community Engagement and Dissemination Core** is Professor of Urban and Regional Planning and an internationally regarded urban planning scholar whose work focuses on community development, inequity in urban communities, affordable housing, and education policy. He has worked with Buffalo East Side communities since he joined the UB faculty in 2003.

The **Steering Committee** of the Center of Excellence will serve as an internal advisory group and includes the Leadership Team in addition to the following accomplished faculty and community leaders:

- **Susan Grinslade PhD RN** is Clinical Professor in the School of Nursing and fellow in the American Academy of Nursing with expertise in public health nursing and a passion for health equity. She led the Million Hearts Initiative in Buffalo (a CDC program to reduce heart disease) facilitating a partnership between the School of Nursing and African American East Side communities.
- **Heather Orom PhD** is Associate Professor of Community Health and Health Behavior and Associate Dean for Equity, Diversity and Inclusion in the School of Public Health. Her research focuses on the causes of health disparities with a particular interest in how discrimination influences health outcomes.
- **Rita Hubbard Robinson JD** is an influential community leader and founder and CEO of NeuWater & Associates, LLC, a company focused on population health. Ms. Hubbard Robinson has been committed to the improvement of health and social determinants of health for over 30 years. She is treasurer of the Buffalo Center for Health Equity and has won numerous awards for her work in the community.
- **Henry Taylor PhD** is Professor of Urban and Regional Planning in the School of Architecture and Planning and is Founding Director for the UB Center for Urban Studies. He is a national authority in distressed urban neighborhoods and race and class issues among people of color. He recently released a comprehensive report on the state of Black Buffalo, “The Harder We Run” that is attracting widespread attention throughout our community, including elected leaders and business leaders (6).
- **Pastor Kinzer Pointer MM,** Co-Director, Investigator Development Core, is President and CEO of Greater Buffalo United Ministries and Chair, Erie County Poverty Committee. He is a mentor in the National Medical Association and has worked for the past five years with Drs. Murphy and Gomez on the T35 training grant “Training the Next Generation of Clinician Scientists.” He co-teaches a course in the medical school with Dr. Henry Taylor, “Health in the Neighborhood,” in which students review key literature and meet with and work with community members in their neighborhoods.

- **Carol Van Zile Tamsen PhD,** Evaluation Director, is Director of the UB Office of Curriculum, Assessment and Teaching Transformation. She is a nationally recognized expert in evaluation and assessment of educational and training programs.

Thus, the Steering Committee includes faculty from multiple disciplines (medicine, public health, nursing, urban planning, evaluation) in addition to well-connected community members. In addition to an advisory role, members of the Steering Committee will serve on mentoring committees of early-career investigators and will identify mentors from their schools for mentoring roles, working with the Investigator Development Core. Drs. Orom, Grinslade, and Taylor and Ms. Hubbard Robinson are Associate Directors of the Health Equity Institute, enhancing coordination with the Center of Excellence. The UB Provost provides full time salary support for a research administrator to the Health Equity Institute and will continue to do so (see Letter of Support). This administrator will work closely with the Center of Excellence Project Manager (see Budget).

Community Advisory Board (CAB). The Health Equity Institute has an active CAB that consists of a group of community members who share an identity, geography, history, or experiences and serve as a voice for the community regarding research, health care, inequities and more. Our Center of Excellence will work with the same CAB since the goals of the Center of Excellence and Health Equity Institute are well aligned. The CAB includes nine people of color, who all live in one of the five predominantly African American ZIP codes on the East Side. Board members serve staggered three-year terms, select their own chair and meet quarterly. The CAB provides feedback in ways to improve research in the community and will provide guidance and direction to the Center of Excellence in realizing its goals. CAB members are paid an hourly rate for their service.

External Advisory Committee will be comprised of three or four national experts who will visit Buffalo annually to review our progress and provide a detailed report.

B4.2 Action Plan for Aim 2

Aim 2. Organize and integrate core initiatives to ensure communication and synergy among cores, while providing expertise and support for maintaining compliance with policies and procedures.

The day-to-day activities of the Center of Excellence will be managed by the director and institute administrator with the active participation of the Leadership Team to ensure coordination of cores through biweekly meetings and regular communication. **Table B1** shows the frequency of meetings of the key leadership and oversight groups to facilitate efficient functioning, anticipation and amelioration of barriers, active partnership with community stakeholders and continuous improvement through constructively critical review by experts on the External Advisory Board. No changes in leadership are anticipated. However, if the PI needs to be replaced, with the involvement of four active, experienced associate directors of the Health Equity Institute, our leadership structure has a built-in succession plan.

Table B1. Frequency of Meetings

Leadership or oversight group	Frequency of meetings
Leadership Team	every 2 weeks
Steering Committee	monthly
NIMHD Program Officer	monthly
Community Advisory Board	quarterly
External Advisory Board	annually

The Steering Committee will meet monthly. Its roles include: 1) guide strategic priorities of the Center of Excellence; 2) work with the Investigator Development Core to identify mentors for early career investigators on pilot studies and subsequent projects; 3) facilitate resources and partnerships to support the goals of the Center of Excellence; 4) form subcommittees to plan and implement selected initiatives-- examples include, conferences, workshops, projects, new partnerships, etc; and 5) act as an initial point of contact for researchers to engage the Center of Excellence, given the broad reach of the committee throughout the university. The Leadership Team appoints members to the Steering Committee in consultation with the VP for Health Sciences to whom the Director reports.

We propose a monthly remote meeting with our Program Officer to ensure that our Center aligns with NIMHD priorities and to enhance communication. The Director, our community-based Co-Director, and administrator will attend. We can also invite Core Directors, depending on the preference of the Program Officer.

The roles of the Community Advisory Board and External Advisory Board are described above.

The Administrative Core will work closely with the Investigator Development Core in fostering research career development and enhancement for postdoctoral fellows, junior faculty and other early-stage investigators by providing support in organizing and administering a variety of educational opportunities. The administrator will

provide support in organizing and coordinating the didactic training outlined in Table C5 (Investigator Development Core), including the seminar series in minority health and health disparities that we will launch with invited outside speakers in addition to experts at UB. These also include an annual Pilot Studies Symposium and an Institute Research Day at which scholars will present their work. We will also facilitate awareness and coordination with valuable educational opportunities beyond our Institute in the university and the community.

Our Center of Excellence will serve as a central resource and point of information for the university and community on educational resources related to research in minority heath and health disparities. Our Administrative Core will link faculty and trainees with educational and training resources by responding to requests and through our website, listserv, social media and word of mouth.

B4.3 Action Plan for Aim 3.

Aim 3. Monitor progress toward milestones through tracking and evaluation to identify opportunities for improvement.

Figure B3 is the overarching logic model that will guide our evaluation and continuous quality improvement.

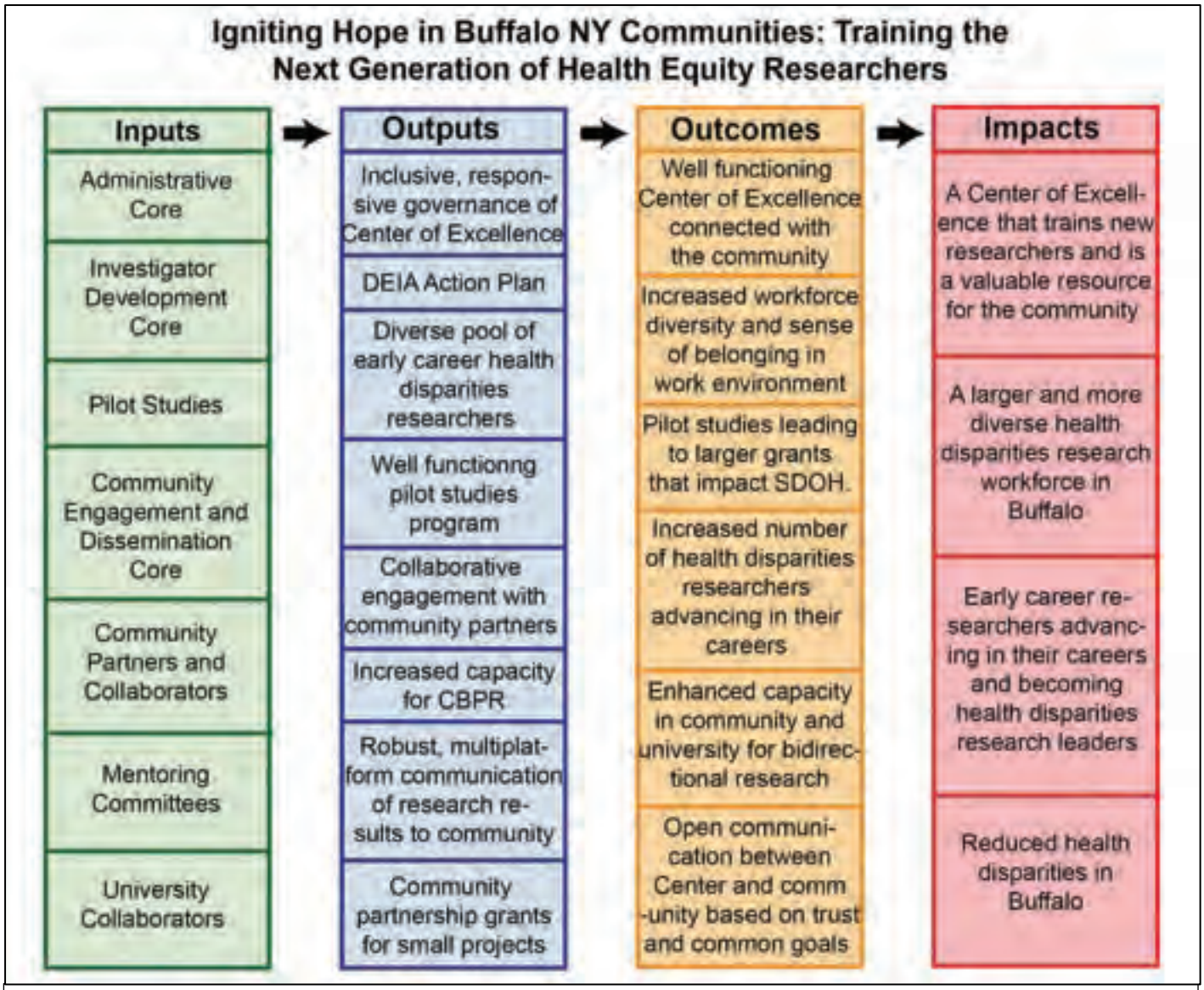


Figure B3. Logic Model for Center of Excellence. DEIA: diversity, equity, inclusion, accessibility. CBPR: community-based participatory research. SDOH: social determinants of health.

The overall evaluation of the Center of Excellence and evaluation plan for each Core are guided by the Program Evaluation Standards (3rd edition) (7). The evaluation plans have been developed using Backward Design to align aims and inputs with key project activities, milestones (short-term outcomes) and long-term impacts (8).

Through this approach, aims/inputs are aligned with desired outputs. Formative assessments of program activities are administered frequently to promote continuous improvement. Summative assessments are used to measure progress toward short-term outcomes and achievement of long-term impacts.

A detailed plan has been developed for all three cores. The evaluation plan for the Investigator Development Core is included here as an example, as page limits preclude showing the evaluation plan for each core.

This overall framework will be used to guide each pilot studies awardee to create an evaluation plan for their pilot projects (1 to 2 years), which focus on specific initiatives that will not yield the long-term impacts outlined in the overall logic model above. Thus, outcomes and impacts will be aligned with realistic goals for the projects. For example, a project may address a specific SDOH (e.g., housing). Realistic goals will be designed to measure outcomes (e.g., reduction in lead poisoning in a specific neighborhood). An effort will be made to link outcomes from work on specific SDOH with specific health outcomes to elucidate causality where possible.

Table B2. Logic Model of Investigator Development Core

Core Aims	Outputs	Short-Term Outcomes	Long-Term Impacts
Aim 1. a. Attract, mentor, and train early career investigators to perform research on health disparities and adverse SDOH. b. Fund pilot projects that address health disparities and adverse SDOH. **Aim 2.** a. Implement a diversity equity, inclusion, accessibility (DEIA) Action Plan. b. Increase and diversify the workforce in health disparities research. c. Create leadership pathways for early career faculty. **Aim 3.** Expert training/mentoring in rigorous research design that includes community-based participatory research.	1a. Recruitment of a diverse pool of early career scientists from a broad range of disciplines. 1b. Implementation of pilot studies grant program. 2a. DEIA action plan for investigators, mentors and staff. 2b. Enhanced programs to increase workforce diversity. 2c. Development of leadership pathways for early career faculty. 3. Fully trained, diverse, and effective pool of early career scientists with an established research agenda related to SDOH and interventions to benefit the local community.	Outcome 1. Fully trained, diverse, and successful junior faculty committed to DEIA. Outcome 2. Research agendas focused on solutions to health disparities and adverse SDOH, generating publications, grants and translatable knowledge/ interventions within the local community. Outcome 3. Diverse and independent scientists prepared for leadership roles in research on minority health and health disparities.	A coherent network of support to promote development of junior faculty and a culture of mentoring. Successful junior faculty engaged in research that promotes equity in health outcomes through amelioration of adverse SDOH. Diverse expert scientists in leadership roles enabling them to positively impact equity in health care and health outcomes. A body of research that addresses health disparities and adverse SDOH and includes community-based research and dissemination of findings.

Table B3. Formative Evaluation. Investigator Development Core

Activities	Measures	Timing	Use of Results
Recruit (Aim 1)	Descriptive data on number, demographics, and disciplines.	Upon recruitment.	Data that can inform improvements in faculty diversity.
Train (Aims 1 & 3)	Attendance/completion of training modules/workshops	End of each training module/workshop.	Identification of necessary improvements.
	Participant Evaluations	End of each training module or workshop.	Identification of areas for further knowledge development and faculty development. Identification of necessary improvements.
Mentor (Aims 1 & 3)	Mentoring Satisfaction and Self-Efficacy Surveys.	At the end of the first six months and the first year.	Review of efficacy of mentoring pairings. Improvement of mentoring training program.
	Interviews/focus groups with mentors and mentees.	At the end of the first year of participation.	Review of efficacy of mentoring pairings. Improvement of mentoring/training.
DEIA, Career and Leadership Development (Aim 2)	Rubric review of DEIA.	End of each year of participation.	Identification of areas for continued development.
	Survey of professional/DEIA goals and career preparation.	End of each year of participation.	Improvement of training/mentoring. Identification of areas for further development.

Fund pilot research on health disparities (Aim 1)	Number and quality of pilot proposals (rubric).	As proposals are reviewed and funded.	Improvement of training/mentoring. Identification of areas for further development.
	Number of projects that develop and assess interventions in key health disparities and adverse SDOH	Upon completion of pilot projects.	Improvement of training/mentoring. Improvement of training/support and communication of Center goals to investigators.
	Number of pilot projects that lead to publications and proposals for NIH- or other federally-funded projects.	Upon completion of pilot projects.	Improvement of training/mentoring. Identification of areas for further knowledge and career development.

Table B4. Summative Evaluation: Short-Term Outcomes. Investigator Development Core

Outcomes	Design	Measures	Timing	Analysis
Outcome 1. Fully trained, diverse, and successful junior faculty committed to DEIA.	Program Records Relevant National/Local Databases	1. Demographics of faculty engaged in relevant research. 2. Number of projects with papers and grants in preparation	Annually after completion of the pilot project.	Descriptive Statistics
Outcome 2. Research agendas focused on health disparities and adverse SDOH and generating translatable knowledge/ interventions within the local community.	Investigator Feedback Form	Number and percent of scholars with community-focused research agendas focused on health disparities and adverse SDOH (scored with rubric).	Annually after completion of the pilot project.	Descriptive Statistics
Outcome 3. Diverse and independent scientists prepared for leadership roles that will provide a platform for advancing health disparities research.	Survey CV Collection	Number and percent of participants with PI/MPI roles on relevant funded projects and established publication records.	Annually after completion of the pilot project.	Descriptive Statistics

Table B5. Summative Evaluation: Long-Term Impacts. Investigator Development Core

Impacts	Design	Measures	Timing	Analysis
A coherent network of support to promote development of early career investigators and a culture of mentoring among senior faculty.	Survey	Ratings of importance and effectiveness in training, mentoring, and professional development for career potential.	Every three years after completion of the pilot project.	Descriptive Statistics
Successful faculty engaged in research that promotes equity in research healthcare and health outcomes	National/Local Databases CV Collection	Number and percent of scholars engaged in relevant research.	Three years after completion of the pilot project.	Descriptive Statistics
A diverse group of expert scientists with strong community engagement in leadership roles that allow them to positively impact equity in research healthcare and health outcomes.	Survey CV Collection	1. Number and percent of participants in leadership roles and reporting strong community engagement. 2. Number and percent of scholars engaged in relevant research.	Every three years after completion of the pilot project.	Descriptive Statistics
A body of research that addresses health disparities and adverse SDOH and includes community-based research and dissemination of findings.	National/Local Databases CV Collection	Number and percent of scholars engaged in relevant research.	Six years after completion of the pilot project.	Descriptive Statistics

Summary and Vision

An NIMHD Center of Excellence fills a critical gap in our training environment. Our vision is the Center of Excellence will provide training, individualized mentoring, and professional development to early-stage investigators to substantially increase the number of investigators in health disparities research. Our Center will also function as a central resource and “go to” to connect research teams and community-based organizations with educational and training opportunities throughout the university and community. Thus, our Center of Excellence will have enormous impact in our environment to address root causes of health inequities and lead to sustainable system-level changes in race-based health inequities in Buffalo and nationally through sharing the innovative interventions that our investigators will develop and test.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	○ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	○ Yes ● No
Is the Project Exempt from Federal regulations?	○ Yes ○ No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

Bibliography: Administrative Core

1. Woolf SH. Progress In Achieving Health Equity Requires Attention To Root Causes. Health affairs. 2017;36(6):984-91. doi: 10.1377/hlthaff.2017.0197. PubMed PMID: 28583955.

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7. Yarbrough DB, Shulha LM, Hopson RK, Caruthers FA. The program evaluation standards: A guide for evaluators and evaluation users. Thousand Oaks, CA: Sage Publications, Inc.; 2010.

8. Wiggins G, McTighe, J. Understanding by Design. New York, N.Y.: Pearson; 2005.

OMB Number: 4040-0001
Expiration Date: 11/30/2025

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **UEI*:** LMCJKRFW5R81

Legal Name*: The Research Foundation for SUNY on behalf of U. at Buffalo
Department: Sponsored Projects Services
Division:
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Amy		Lagowski	

Position/Title: Agreement Administartor
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567
Phone Number*: 716-645-4419 Fax Number: Email: amy.lagowski@buffalo.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): Private, Non-profit

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers

12. PROPOSED PROJECT

Start Date*	Ending Date*
04/01/2024	03/31/2029

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Research Foundation for SUNY on behalf of U. at Buffalo
UEI:	LMCJKRFW5R81
Street1*:	The UB Commons
Street2:	520 Lee Entrance, Suite 211
City*:	Amherst
County:	Erie
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14228-2567
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB Clinical and Translational Research Center
UEI:	
Street1*:	875 Ellicott Street Buffalo
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14203-1034
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Jacobs School of Medicine and Biomedical Sciences
UEI:
Street1*: 955 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1034
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Public Health and Health Professions
UEI:
Street1*: 3435 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3099
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 4

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Nursing
UEI:
Street1*: 3435 Main Street- Wende Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3010
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 5

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Architecture and Plannning
UEI:
Street1*: 3435 Main Street- Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3015
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 6

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Community Health Equity Research Institute
UEI:
Street1*: 875 Ellicott Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1070
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 7

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Buffalo Center for Health Equity
UEI:
Street1*: 257 West Genesee Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14202-2657
Project/Performance Site Congressional District*: NY-026

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ○ **Yes** ● **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ○ No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Abstract_Comm_Engage.pdf
8. Project Narrative*	
9. Bibliography & References Cited	Bibliography_CEDC.pdf
10.Facilities & Other Resources	
11.Equipment	

The Community Engagement and Dissemination Core (CEDC) will facilitate equitable collaborative and sustainable relationships with community partners and other stakeholders. Universities have long considered community engagement as a social responsibility. A more comprehensive approach to working with communities is required to shift the narrative from viewing communities as groups of people who have needs to recognizing them as assets. Engaged communities can show institutional leaders and researchers how to better understand and address social determinants of health and increase the impact of research discoveries. This is the approach that our NIMHD Center of Excellence in Investigator Development and Community Engagement will take. Our activities will be undertaken in collaboration with our community-university-government partnership, a collaboration established in 2014 involving multiple sectors of the community. The active participation of community and elected leaders will be particularly impactful in translating the results of our research into measurable impact in health disparities in Buffalo. The CEDC will aid investigators and community co-investigators during the planning and conduct of research to build community-based participatory research capacity (Aim 1). Working with the Investigator Development Core the CEDC will work with each pilot study awardee to 1) provide training in working with the community, 2) link scholars with key community partners in the planning stages of their project, 3) develop a dissemination plan for their project to be implemented during the project and after it is completed, and 4) plan and implement an approach for their work to lead to actual benefit to the community. This often involves the planning of a larger project facilitated by the pilot study, which in many cases provides key preliminary data for the larger project. The CEDC will work with research teams in sharing results of research for diverse audiences, including non-scientific community members, policy makers and community-based stakeholders in translating research findings to promote sustainable community- and system-level change (Aim 2). We will work closely with the community-based Buffalo Center for Health Equity who have an extensive communications network with broad reach into the community. The CEDC will offer small Community Partnership Grants to African American led community-based organizations to support neighborhood projects designed to mitigate health inequities (Aim 3). This initiative arose from planning discussions with community members who expressed a clear interest in working with the Center of Excellence to build capacity and develop critical infrastructure in community-based organizations and bring immediate visible benefit to community members. Our five-year vision is that the Center of Excellence will catalyze a transformation of community-based research by expanding our research workforce, training future leaders in the field, and creating a culture change by influencing UB researchers to design research to address root causes of health inequities and work toward translating findings into sustainable, system-level changes.

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Robert Middle Name Last Name*: Silverman Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department: Urban and Regional Planning
Division:
Street1*: 329 Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8030

Phone Number*: (716) 829-5882 Fax Number:

E-Mail*: rms35@buffalo.edu

Credential, e.g., agency login: SILVERMAN35

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Heather Middle Name Last Name*: Orom Suffix: Ph.D

Position/Title*: Associate Professor
Organization Name*: SUNY at Buffalo
Department: Community Health and Health Behavior
Division: School of Public Health and Health Professions
Street1*: 304 Kimball Tower
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8028

Phone Number*: (716) 829-6682 Fax Number:

E-Mail*: horom@buffalo.edu

Credential, e.g., agency login: ay6457

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Susan Middle Name Last Name*: Grinslade Suffix: Ph.D

Position/Title*: Associate Director
Organization Name*: SUNY at Buffalo
Department: UB Community Health Equity Research Institute
Division: School of Nursing
Street1*: 210 Wende Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3079

Phone Number*: 716-829-2234 Fax Number:

E-Mail*: msgrinsl@buffalo.edu

Credential, e.g., agency login: MGRINSLADE

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Henry Middle Name Louis Last Name*: Taylor Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department: Urban and Regional Planning
Division:
Street1*: 330A Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8030

Phone Number*: (716) 829-5458 Fax Number:

E-Mail*: htaylor@buffalo.edu

Credential, e.g., agency login: HLTAYLOR

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Christopher Middle Name Last Name*: St. Vil Suffix: Ph.D

Position/Title*: Assistant Professor
Organization Name*: SUNY at Buffalo
Department:
Division: UB School of Social Work
Street1*: 625 Baldy Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14260-1000

Phone Number*: 716-645-9091 Fax Number:

E-Mail*: cstvil@buffalo.edu

Credential, e.g., agency login: CSTVIL

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Robert		Silverman	Ph.D	Co-investigator	129,394.00		1.0		7,189.00	4,705.00	11,894.00
2.	Christopher		St. Vil	Ph.D	Co-investigator	94,057.00		0.6		3,135.00	2,052.00	5,187.00
3.	Heather		Orom	Ph.D	Co-Investigator	145,349.00	0.6			3,634.00	2,378.00	6,012.00
4.	Henry		Taylor	Ph.D	Co-investigator	186,567.00	0.6			4,664.00	3,053.00	7,717.00
5.	Margaret	Susan	Grinslade	Ph.D	Co-investigator	158,472.00	0.6			3,962.00	2,593.00	6,555.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **37,365.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**37,365.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Communication Expenses	10,000.00
Total Other Direct Costs	**24,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**61,365.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	61,365.00	37,434.00
		Total Indirect Costs	**37,434.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**98,799.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	98,799.00

L. Budget Justification*	File Name: Budget_Justification-Community_Engagement.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Robert		Silverman	Ph.D	Co-investigator	131,981.00		1.0		7,189.00	4,805.00	11,994.00
2.	Christopher		St. Vil	Ph.D	Co-investigator	95,939.00		0.6		3,135.00	2,095.00	5,230.00
3.	Heather		Orom	Ph.D	Co-Investigator	148,256.00	0.6			3,634.00	2,429.00	6,063.00
4.	Henry		Taylor	Ph.D	Co-investigator	190,298.00	0.6			4,664.00	3,117.00	7,781.00
5.	Margaret	Susan	Grinslade	Ph.D	Co-investigator	161,641.00	0.6			3,962.00	2,648.00	6,610.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **37,678.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**37,678.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Communication Expenses	10,000.00
Total Other Direct Costs	**24,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**61,678.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	61,564.00	37,624.00
		Total Indirect Costs	**37,624.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**99,302.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	99,302.00

L. Budget Justification*	File Name: Budget_Justification-Community_Engagement.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Robert		Silverman	Ph.D	Co-investigator	134,621.00		1.0		7,189.00	4,909.00	12,098.00
2.		Christopher		St. Vil	Ph.D	Co-investigator	97,857.00		0.6		3,135.00	2,141.00	5,276.00
3.		Heather		Orom	Ph.D	Co-Investigator	151,221.00	0.6			3,634.00	2,481.00	6,115.00
4.		Henry		Taylor	Ph.D	Co-investigator	194,104.00	0.6			4,664.00	3,185.00	7,849.00
5.		Margaret	Susan	Grinslade	Ph.D	Co-investigator	164,874.00	0.6			3,962.00	2,705.00	6,667.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **38,005.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**38,005.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

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RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Communication Expenses	10,000.00
Total Other Direct Costs	**24,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**62,005.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	62,005.00	37,823.00
		Total Indirect Costs	**37,823.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**99,828.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	99,828.00

L. Budget Justification*	File Name: Budget_Justification-Community_Engagement.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Robert		Silverman	Ph.D	Co-investigator	137,313.00		1.0		7,189.00	4,909.00	12,098.00
2.	Christopher		St. Vil	Ph.D	Co-investigator	99,814.00		0.6		3,135.00	2,141.00	5,276.00
3.	Heather		Orom	Ph.D	Co-Investigator	154,246.00	0.6			3,634.00	2,481.00	6,115.00
4.	Henry		Taylor	Ph.D	Co-investigator	197,986.00	0.6			4,664.00	3,185.00	7,849.00
5.	Margaret	Susan	Grinslade	Ph.D	Co-investigator	168,171.00	0.6			3,962.00	2,705.00	6,667.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **38,005.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**38,005.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Case 1:25-cv-10814-WGY Document 12-24 Filed 04/04/25 Page 224 of 375

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Communication Expenses	10,000.00
Total Other Direct Costs	**24,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**62,005.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	62,005.00	37,823.00
		Total Indirect Costs	**37,823.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**99,828.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	99,828.00

L. Budget Justification*	File Name: Budget_Justification-Community_Engagement.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Robert		Silverman	Ph.D	Co-investigator	137,313.00		1.0		7,189.00	4,909.00	12,098.00
2.		Christopher		St. Vil	Ph.D	Co-investigator	99,814.00		0.6		3,135.00	2,141.00	5,276.00
3.		Heather		Orom	Ph.D	Co-Investigator	154,246.00	0.6			3,634.00	2,481.00	6,115.00
4.		Henry		Taylor	Ph.D	Co-investigator	197,986.00	0.6			4,664.00	3,185.00	7,849.00
5.		Margaret	Susan	Grinslade	Ph.D	Co-investigator	168,171.00	0.6			3,962.00	2,705.00	6,667.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **38,005.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**38,005.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Case 1:25-cv-10814-WGY Document 12-24 Filed 04/04/25 Page 227 of 375

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	14,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Communication Expenses	10,000.00
Total Other Direct Costs	**24,000.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**62,005.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	62,005.00	37,823.00
		Total Indirect Costs	**37,823.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**99,828.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	99,828.00

L. Budget Justification*	File Name: Budget_Justification-Community_Engagement.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Budget Justification: Community Engagement and Dissemination Core

NOTE: We share, with approval of the NIH grants management specialist, that we have committed $794,696 in institutional support vis personnel efforts. It was our intent to include key personnel from multiple disciplines as well as compensate community partners equally to faculty. With this purpose, and $300,000 committed to pilot awards, we sought support from the university to maintain a balanced and robust budget.

A. Personnel Salaries and Wages

Senior/Key Personnel

Robert Silverman, PhD

- Director, Community Engagement and Dissemination Core
- Effort: 1.0 academic months (Institutional support years 1-5: 0.50 academic months)

Dr. Silverman is Professor of Urban and Regional Planning in the School of Architecture and Planning He is an internationally regarded urban planning scholar whose work focuses on community development, inequity in urban communities, affordable housing, and education policy. He has worked closely with Buffalo East Side Communities since he joined the UB faculty in 2003.

Responsibilities

- Lead the Community Engagement and Dissemination Core
- Facilitate linking of pilot studies awardees with community partners
- Work with Buffalo Center for Health Equity on dissemination of research results to community
- Work with Administrative Core in reviewing and managing the Community Partnership grants

Stan Martin, MM

- Co-Director, Community Engagement and Dissemination Core
- Effort: Independent Contractor

Stan Martin is Co-Director, Buffalo Office Director and Senior Trainer at Ciccatelli Associates Inc. He directs a five-year Racial and Ethnic Approaches to Community Health (REACH) grant from the CDC that focuses on the promotion of tobacco-free living, improved nutrition and community support for breastfeeding, and increased access to health care in Buffalo East Side neighborhoods. His group holds frequent community events, workshops, and informational sessions with community members.

Responsibilities:

- Co-Director of Community Engagement and Dissemination Core (CEDC)
- Provide guidance and contribution to CEDC
- Facilitate community conversations to help guide pilot studies program
- Serve on Center of Excellence Steering Committee

Henry Taylor, PhD

- Co-Investigator, Community Engagement and Dissemination Core
- Co-Investigator, Investigator Development Core
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Taylor is Professor of Urban and Regional Planning, School of Architecture and Planning, Director of the Center for Urban Studies; and Associate Director, UB Community Health Equity Research Institute. His areas of expertise include urban development, housing, gentrification, underdeveloped neighborhoods, shrinking cities, race and class, and U.S.-Cuba relations. His research focuses on a historical and contemporary analysis of underdeveloped urban neighborhoods, social isolation, and race and class issues among people of color, especially African Americans and Latinos. Dr. Taylor designed and conducts the *Urban Internship Program,* which creates opportunities for graduate and undergraduate students to become involved in neighborhood redevelopment initiatives and research projects. He has trained

numerous students in this program over the years. He is also the Co-leader of the CTSI Workshop series in Health Equity.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Provide guidance and contribution to the Investigator Development Core
- Serve on Center of Excellence Steering Committee
- Serve as Center of Excellence advocate to selected pilot studies awardees
- Facilitate partnerships and collaborations in the School of Architecture and Planning
- Help identify mentors for pilot studies awardees as needed

Heather Orom, PhD

- Co-Investigator, Community Engagement and Dissemination Core
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Orom is Associate Professor of Community Health and Health Behavior and Associate Dean for Equity, Diversity and Inclusion in the School of Public Health. Her research focuses on the causes of health disparities with a particular interest in how discrimination influences health outcomes. Dr. Orom has led many projects and has collaborated on many projects that have advanced understanding of health inequities. She engages in applied health equity research for local community organizations, assisting with evaluation and other research needs. Dr. Orom is an Associate Director of the Community Health Equity Research Institute

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships and collaborations in the School of Public Health and Health Professions
- Serve on Center of Excellence Steering Committee

Susan Grinslade, PhD, RN

- Co-Investigator, Community Engagement and Dissemination Core
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Grinslade is Clinical Professor in the School of Nursing and fellow in the American Academy of Nursing with expertise in public health nursing and a passion for health equity. She is also an Associate Director of the Community Health Equity Research Institute. She led the Million Hearts Initiative in Buffalo (a CDC program to reduce heart disease) facilitating a partnership between the School of Nursing and African American East Side communities. She has particular expertise in community based participatory research. Dr. Grinslade was an original member of the African American Health Equity Task Force and was instrumental in connecting UB faculty with the Task Force.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships and collaborations in the School of Nursing
- Provide guidance on community based participatory research
- Serve on Center of Excellence Steering Committee

Christopher St. Vil, PhD

- Co-Investigator, Community Engagement and Dissemination Core
- Effort: 0.60 academic months (Institutional support years 1-5: 0.30 academic months)

Dr. St.Vil is Associate Professor in the School of Social Work. He is an expert on trauma and victims of violent injury, masculinities and health, gun violence, risk-taking attitudes and social welfare inequities in

African American communities. Dr. St. Vil leads the SNUG program at Erie County Medical Center, the safety net hospital in Buffalo. SNUG is an evidence-based street outreach program, which treats gun violence like a disease by identifying its causes and interrupting its transmission. The SNUG team develops and implements risk-reduction strategies to reduce involvement with gun violence with the goal of saving lives and helping individuals turn their lives around.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships and collaborations in the School of Social Work

Kelly Wofford, MS

- Collaborator, Community Engagement and Dissemination Core
- Effort: Independent Contractor

Kelly Wofford is Director, Office of Health Equity in the Erie County Department of Health. Before joining the Erie County Department of Health, she was the Community Engagement Coordinator of the UB School of Nursing and the Director of Community Relations for the Erie County Medical Center. She has a particular interest in mental health equity and is an active participant in the African American Health Equity Task Force.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Work with the Investigator Development core to identify mentors for early career investigators
- Facilitate partnerships with community members and organizations
- Work with the Center of Excellence on developing strategies to implement policy changes based on results of research as appropriate based on results

Other Personnel

Other Direct Costs

Communication expenses $10,000

Dissemination of research results and communication with community members is a critical goal of our community Engagement and Dissemination Core. Expenses will be for printed material and online and social media strategies of reaching our community audience.

Data Management and Sharing
No costs to be incurred. Campus resources will be utilized.

Fringe Benefits
Fringe benefit rates are based on the applicable state and federally negotiated rates."

Indirect Costs
The indirect costs are calculated at the University at Buffalo predetermined Facilities and Administrative (F&A) cost rate of MTDC per DHHS agreement dated 04/27/2023.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		18. ,058h00
Section B, Otuer Personnel		0h00
Total Nmb ger Otuer Personnel	0	
Total Salary, Wades anf Frinde Bene+its (AqB)		18. ,058h00
Section C, Epmivb ent		0h00
Section D, Tra7el		0h00
1. Domestic	0h00	
2hForeidn	0h00	
Section E, Particivant/Trainee Smvvort Costs		0h00
1hTmition/Fees/Healtu Insmrance	0.00	
2hStivenf s	0h00	
3hTra7el	0h00	
4hSmgsistence	0h00	
5hOtuer	0h00	
6hNmb ger o+Particivants/Trainees	0	
Section F, Otuer Direct Costs		120,000h00
1hMaterials anf Smvvlies	0h00	
2hPmglication Costs	0h00	
3hConsmltant Ser7ices	90,000h00	
4hADP/Cob vmter Ser7ices	0h00	
5hSmgawarf s/Consortimb /Contractmal Costs	0h00	
6hEpmivb ent or Facility Rental/User Fees	0h00	
9hAlterations anf Reno7ations	0h00	
8hOtuer 1	50,000h00	
. hOtuer 2	0h00	
10hOtuer 3	0h00	
11hOtuer 4	0h00	
12hOtuer 5	0h00	
13hOtuer 6	0h00	
14hOtuer 9	0h00	
15hOtuer 8	0h00	
16hOtuer .	0h00	
19hOtuer 10	0h00	
Section G, Direct Costs (A turmF)		30. ,058h00
Section H, Inf irect Costs		188,529h00

Section I, Total Direct anf Inf irect Costs (G q H)	4. 9,585h00
Section J, Fee	0h00
Section K, Total Direct anf Fee (I q J)	4. 9,585h00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 01/31/2026

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PNS y9C Research Plan

V/ x : umberEK926-KKK1
3Hpiration gateEK18y182K2M

Introduction

1. Introduction to Application
(for Resubmission and Revision applications)

Research Plan Section

2. Specific Aims	AIms_03gO.pdf
y. Research Strate* 04	O3gO_Research_Strate* 0.pdf
L. Pro* ress Report Publication 5ist	

Vther Research Plan Section

6. 7ertebrate Animals

M Select A* ent Research

D. / ultiple Pg8PI 5eadership Plan

C. Oonsortium8Oontractual Arran* ements

9. 5etters of Support

1K. Resource Sharin* Plan(s)

11. Vther Plan(s)

12. Authentication of Be0 x iolo* ical and8or Ohemical Resources

AppendiH

1y. AppendiH

D. Community Engagement and Dissemination Core

D1. Specific Aims

The Community Engagement and Dissemination Core (CEDC) will facilitate equitable collaborative and sustainable relationships with community partners and other stakeholders. Our approach to community-based participatory research (CBPR) is informed by the broad literature on participatory action research and CEDC team members' experience with praxis. The CEDC will have two foci encapsulated in Aims 1 and 2. Aim 1 activities are designed to aid university-based and community-based investigators (pilot studies PIs and Co-Is) to build CBPR capacity. Simultaneously, in Aim 2 the CEDC will coordinate dissemination of activities with investigators, community members, community-based organizations, service organizations, policymakers, and the scientific community with a goal to facilitate the translation of findings into sustainable community and system-level changes. To do this, the CEDC will use community organizing techniques to link the dissemination of research results to grassroots efforts to translate those results into policy change at the local level and beyond. Aim 3 resulted directly from the planning discussions for this proposal to fund small grants to community-based organizations to support neighborhood projects designed to mitigate specific inequities.

Our activities will be done in collaboration with the African American Health Equity Task Force (Task Force), a collaboration established in 2014 involving multiple sectors of the community (**Figure D1**). The active participation of community and elected leaders will be particularly impactful in translating the results of our research into measurable impact in health disparities in Buffalo, NY (see Overall).



Figure D1. African American Health Equity Task Force

The CEDC will accomplish the following Aims:

Aim 1. Aid investigators and community co-investigators during the planning and conduct of research to build community-based participatory research (CBPR) capacity.

Aim 2. Work with research teams in sharing results of research for diverse audiences, including non-scientific community members, policy makers and community-based stakeholders in translating research findings to promote sustainable community- and system-level change.

Aim 3. Offer small Community Partnership Grants to African American led community-based organizations to support neighborhood projects designed to mitigate health inequities.

- This initiative arose from planning discussions with community members who expressed a clear interest in working with the Center of Excellence to build capacity and develop critical infrastructure in community-based organizations and bring immediate visible benefit to community members.

D2. Significance

The traditional tripartite mission of academic health centers of education, clinical care and research does not address the most important factors accounting for shorter life expectancy and poorer health in communities of color. Socioeconomic, environmental and geographic factors play vital roles in population health. Thus, addressing the social determinants of health (SDOH) and equity where their patients live, work and play is the fourth fundamental component of the mission of academic health centers. For far too long, academic health centers and universities viewed communities as people who have needs and working with communities was viewed as solely a social responsibility. Our proposal takes a comprehensive approach to working with communities, wherein we recognize the community is an asset to show institutional leaders and researchers how to understand and address SDOH, advance trainees' ability to provide care, and increase the impact of our research discoveries (2, 3). Our approach is based on this principle.

The Community Engagement and Dissemination Core (CEDC) has three particularly distinctive features. First, the CEDC team's work is guided by the *participatory action research (PAR) paradigm,* which focuses on linking community-based research to community organizing activities (4). The goal of PAR is to use collaborative, non-hierarchal research designs to promote social change and eradicate inequality in society. This philosophy where community engagement is built into empirical research methods and community organizing activities growing out of them is embedded in the CEDC's work (5). We view research projects and community organizing activities as iterative, a distinguishing feature of our approach to community-based participatory research (CBPR). We view the PAR paradigm as a guiding principle (6-9).

The second distinguishing feature of the CEDC is an *intentionally interdisciplinary composition*, including members from academia, professional practice and the broad community. Members of the team come from the health sciences, public health, social work, urban planning and aligned fields. An interdisciplinary team facilitates communication between researchers, practitioners, community members and other stakeholders. This type of 'participatory interdisciplinarity' has been identified as a critical dimension of research and program design to break down barriers to translating knowledge into policy interventions (10). In essence, the existence of an interdisciplinary team facilitates the dissemination of research results and other products from the CEDC's work in a format devoid of jargon and technical language and accessible to a broad audience.

The third distinguishing feature of the CEDC is a commitment to *empowering members of the African American community* in Buffalo across research and community organizing activities. A central tenant is to embed community members as co-investigators and collaborators on research and leverage results to enhance community organizing efforts. We draw from community organizing techniques focused on community empowerment and grassroots leadership development (9,10,11,12) to pursue this goal. The partnership of the Center of Excellence with the community-based Buffalo Center for Health Equity is a key asset in this regard in view of the broad reach into many sectors of the Buffalo community enabling effective advocacy for change.

D3. Innovation

Our model is based on a three-pronged approach to community engagement.

- ***Infusing members of the African American community into the research process*** is the first prong (Aim 1) to strengthen research design by grounding it in the context of the African American experience. Fostering bidirectional conversations between university and community investigators adds dimension to research design, analysis, and strategies for disseminating research results. The CEDC will play a central role in building CBPR capacity and bidirectional interactions between investigators and community co-investigators.
- ***Building community organizing capacity in the African American community*** is the second prong Aim 2)**,** which focuses on linking the dissemination of research results to policy change to address race-based health inequities in Buffalo. This goal extends beyond immediate benefits from research results and has broader implications for capacity building and leadership development in African American civic organizations, enhancing levels of empowerment and community control in local policy domains. The broad reach of the Buffalo Center for Equity into the community and their experience in advocacy will substantially increase the likelihood that our work will lead to changes in policy and ultimately systemic change.
- ***Building the capacity of African American led community-based organizations*** is the third prong (Aim 3), which focuses on. small Community Partnership Grants awarded to these organizations to support the implementation of applied neighborhood projects designed to reduce health inequities. Small grants will bridge an important gap in the implementation of projects and programs aimed at addressing health inequities and bring visible benefit directly to people living East Side neighborhoods.

These three prongs are iterative and mutually reinforcing. The fusion of CBPR capacity building in research, community organizing in the African American community and the development of projects in African American led community-based organizations answers the call for methodological innovations that improve the translation and dissemination of research on health inequities (2, 11, 12).

Evaluation tools for community-based research on health inequities. There is a lack of in-depth analysis of the social transformative potential of CBPR (13). Our focus on wedding CBPR capacity-building in health equity research with dissemination and advocacy through community organizing in the African American community provides an opportunity for innovations in evaluation research. We will build on past research (14, 15) and develop a model for evaluation of the social transformative potential of public deliberations in health inequities.

D4. Action Plan for Aims

D4.1. Action Plan for Aim 1

Aim 1. Aid investigators and co-investigators from the community during the planning and conduct of research to build community-based participatory research (CBPR) capacity.

Investigators: We will work with investigators in the project planning stages to link them with community partners and refine CBPR elements of their projects. We will provide consultation to investigators who are preparing letters of intent for pilot studies and those applicants whose letters of intent were chosen to submit full proposals. We will also work with postdocs and junior faculty who are interested in pursuing research in health disparities but are new to the discipline. We will work with the Investigator Development Core to link them with faculty mentors with well-established research programs in health disparities. We view this as an excellent strategy for bringing new investigators into the field of health disparities research.

Other research and training resources. Multiple other UB groups offer valuable research and educational opportunities in the form of seminars, workshops, courses, certificates, digital badges, micro-credentials, degree-granting programs and others. The Center for Urban Studies and CTSI are especially relevant:

- **Center for Urban Studies**, founded by Dr. Henry Taylor (CEDC Co-I) in 1987, became formally affiliated with the Community Health Equity Research Institute in 2021. This Center's vision is "to build healthy communities and to create just cities and metropolitan regions" and engaged in community-based research for over three decades. Many graduate students in urban planning completed thesis projects in this Center.
- **Clinical Translational Science Institute (CTSI)** supported by an NIH clinical and translational science award and led by Dr. Murphy (PI of this program) has a vision "to advance and accelerate research to reduce health disparities and improve the health of our community and the nation." The CTSI offers expert support available to faculty at no charge, including biostatistics, epidemiology and research design; regulatory support (e.g., writing IRB protocols); and more. The CTSI *w*orkshops on research design, biostatistics; responsible conduct of research; community engagement; community-university collaborations; health equity; and others are open to all. Pilot studies awardees are required to complete the series on health equity.

In addition, numerous other relevant resources are available to scholars (**Table D1**). The Center of Excellence will connect researchers with resources based on individual needs. The Health Equity Institute website will serve as a central point of information for seminars, workshops, etc. for the UB community and wider Buffalo community.

Table D1. Examples of Relevant University Resources Available to Scholars

Resource	Description	UB Home
Community for Global Health Equity	Scholarly community with an aim to improve peoples' lives around the world	VP for Research and Economic Development
Office of Inclusive Excellence	Students, faculty, & staff partner to build a culture of diversity, social justice, inclusion	Office of the Provost
Center for Diversity Innovation	Translates research on DEI to best practices through educational materials, trainings and consultations	Office of the Provost
Micro-credential in Strategies for Eliminating Health Inequities	Micro-credentials differentiate students and appear on digital resumés, Linked-In accounts and e-portfolios	School of Public Health and Health Professions
Buffalo HealthCast	Weekly health equity podcast by students and faculty	School of Public Health and Health Professions
Center for Inclusive Design and Environmental Access	Develop knowledge & tools to improve health, wellness & participation of groups marginalized by traditional design.	School of Architecture and Planning
Immigrant and Refugee Research Institute	Create and share knowledge on immigrants and refugees to improve their lives with a focus on WNY newcomers	School of Social Work

Community Co-Investigators: We will assist with project specific training for co-investigators from the community who are engaged in pilot study projects. The CEDC will link early career investigators with existing resources at UB for CBPR capacity-building that augments the proposed work of this program. We anticipate a substantial proportion of pilot studies applicants will be new faculty and will benefit from learning and leveraging existing resources at UB to enhance their research over and above the UB Community Health Equity Research Institute in which our Center of Excellence is embedded.

D4.2 Action Plan for Aim 2

Aim 2. Work with research teams in sharing results of research for diverse audiences, including non-scientific community members, policy makers, and community-based stakeholders in translating research findings to promote sustainable community- and system-level- change.

Overall dissemination strategy. Simply defined, dissemination is getting research results to people who can benefit from the findings (16). Dissemination by researchers most often occurs through scientific publications and presentations at scientific conferences. While these approaches are important to ensure that the science withstands peer review, these venues limit the reach to many who could benefit from knowing the results, such as research participants, policy makers and the general public. Communicating research results beyond the traditional academic and scientific audience is a critical component of research dissemination, especially if the results are going to lead to changes in practice. We view dissemination of our research results to the community as an ethical responsibility.

We will reach out to each pilot studies PI to create a well thought out dissemination plan. To be most effective, a dissemination plan should begin during the planning stages of the study (17). Participants in clinical studies consistently express a strong interest in hearing updates on the project in which they are participating. We will work with investigators to develop plans to provide project updates to study participants and other key stakeholders, being careful to adhere to guidelines regarding communicating main study results prior to publication. Maintaining stakeholder engagement during a study is an important component of a comprehensive dissemination plan.

Disseminating research findings. Upon study completion, the CEDC will work with the research team to write a "research summary document" that clearly and concisely summarizes the main findings of a study. This document is a key component of the dissemination strategy which can summarize a single study or may combine several studies performed by the same investigator. The research summary document generally includes key findings using three to five bullet points. Each bullet point can link to more detailed information. The CTSI has an active plain language initiative with tip sheets and experts who work with research teams on developing clear communication materials for lay audiences. We will make liberal use of engaging infographics and illustrations using best practices (18). In addition, the UB Artificial Intelligence (AI) Institute developed innovative AI approaches to creating plain language communications. We will partner with the UB CTSI and AI Institute on selected projects. In addition, we will work with UB Communications, which is active in disseminating research results to lay audiences.

Table D2. Strategies to disseminate research findings to communities

- Press release
- Research summary document
- Flyers, posters, brochures
- Social media
- Policy briefs
- Study newsletters
- Websites and listservs
- Community agency publications
- Local events and community meetings
- Letter of thanks to participants

The strategy for dissemination of findings will be guided by the study. The overall strategy is to distill complex research findings into accessible pieces of relevant information delivered by multiple avenues (**Table D2**). For studies to be published in high impact journals (e.g., JAMA, New England Journal of Medicine, etc.), the CEDC will work with UB Communications on a press release. For studies with immediate potential for policy change, we will work with the PI in composing policy briefs and communicating with the appropriate government agency or elected leader (see Administrative Core and Letters from partner elected leaders).

Table D3. Strategies to communicate research results through social media

- Understand target audience
- Clear and concise message
- Use visual content
- Tell stories
- Encourage questions
- Use diverse social media platforms
- Harness hashtags for visibility
- Track analytics

Social media will play a prominent role in our communication strategy (**Table D3**). Black individuals use social media at a higher rate than other racial groups globally (19). We will work with the research team

to understand key target audiences to tailor content and strategy. We work closely in communication strategies with the Buffalo Center for Equity, which has extensive reach throughout the Buffalo community, including an active social media network. They have a social media expert on staff with whom we work. **Table D3** shows an overview of approaches that we will use.

During the course of the pilot studies projects, the CEDC will reach out proactively to research teams and discuss the potential impact of the project and an implementation plan. We will connect the research team with the appropriate stakeholder to discuss and develop a strategy for next steps in translating the research results into meaningful community change. In some circumstances, this may involve reaching out to government, businesses, community groups, etc., depending on the nature of the research. Our community-university-government partnership will be especially valuable in facilitating these relationships and discussions (see Overall).

A Successful Dissemination Strategy
The Center for Urban Studies released a report by Dr. Henry Taylor (Co-I) entitled "The Harder We Run: The State of Black Buffalo in 1990 and the Present" in 2021 (1). The report examined socioeconomic conditions in Black neighborhoods in Buffalo, including their relationship to health inequities. The dissemination strategy included a press release from the UB Office of Communications, stories on multiple UB online newsletters, circulation of the report, and an in-person/remote community forum hosted by the Buffalo Center for Health Equity. The report generated enormous media coverage, including editorial articles in print media and interviews and coverage on local and national news broadcasts. Working groups including community- and university-based leaders were formed to address the recommendations and Dr. Taylor has written a proposed detailed comprehensive strategic plan "This Time It Will Be Different, The Good Neighborhood Demonstration Project" The draft is under review by community leaders.

Translation of research into sustainable changes through partnerships with government, intermediaries, and local policy makers. In addition to disseminating results of our research to communities, accomplishing our overall goal of reducing health disparities requires that the results of our research be implemented into real-world clinical, community, and public health settings. However, implementation of policy changes in healthcare is often slow, undervalued, incomplete, and inefficient, with the populations most impacted by health disparities typically being the last to have access to innovations, despite having the greatest need. The CEDC team and community partners cultivated a powerful network of partnerships with local government, intermediary organizations, and other local policy makers for the translation of research results. The African American Health Equity Task Force has especially broad reach (**Figure D1**). We sustain a partnership with the Local Initiative Support Corporation (LISC) of Western New York, a national nonprofit intermediary organization that assists in the planning, implementation, and capacity building of public-private community development projects. The Community Health Equity Research Institute has well established community partnerships that are each represented on the Board, along with a leader of each of the 12 UB schools (see Administrative Core). These partnerships are particularly important since they provide avenues for disseminating and translating research results in community and clinical settings.

The inclusion and active participation of public officials and elected leaders, in the African American Health Equity Task Force (Director of the Erie County Health Equity Office, a representative of the office of state Senator Tim Kennedy and the Deputy Mayor of the city of Buffalo) provides a direct line of communication to influential policy makers. We will leverage these partnerships in engaging in critical discussions regarding the research results of our pilot studies awardees with potential to lead to policy changes. Two examples in which these partnerships led to community changes:

- Zeneta Everhart, Director of Community Engagement in the office of State Senator Tim Kennedy, attends monthly Task Force meetings and also the annual *Igniting Hope* conferences on health disparities (see Overall) and participates in breakout discussions. A fines and fees breakout group identified discriminatory policies by the city of Buffalo in ticketing for routine traffic violations in African American East Side Buffalo neighborhoods, leading to driver's license suspensions for unpaid tickets. Ms. Everhart brought this discriminatory policy to the attention of Senator Kennedy leading to a new state law that he authored and sponsored, which led to policy change in traffic ticketing in the East Side of Buffalo (20).
- In 2023, the shocking revelation that the Water Board of the City of Buffalo had not been adding fluoride to its drinking water for the last 7.5 years came to light, explaining the recent increase in dental decay in children living in Buffalo, noted by area pediatric dentists. Following this revelation, Kelly Wofford, Director of the Erie County Office of Health Equity, contacted PI Murphy asking for advice regarding experts who could help with

a mitigation plan until water was again fluoridated. PI Murphy engaged Dr. Joseph Giambacorta, Associate Dean for Community Engagement in the UB School of Dental Medicine and an expert in fluoride and tooth decay. The three met along with other team members to develop a plan, which will involve the participation of UB dentists, to mitigate this disturbing inequity until the Buffalo water supply is properly re-fluoridated (which is now in progress). While this is not technically a result of research, it is an example of community benefit enabled by our enduring partnership, trust ,and bidirectional communication.

D4.3 Action Plan for Aim 3

Aim 3. Offer small, Community Partnership Grants to African American led community-based organizations to support neighborhood projects designed to mitigate health inequities.

During the discussions of pilot studies in the planning of this proposal, community members expressed a clear interest in support for small pilot grants that 1) are in direct response to a community need, 2) are visible to the community and 3) have an immediate positive effect on day-to-day life of the people impacted by the grant. Examples might be purchasing curricular materials and supplies to support the work of a tutor in an after-school program, recreational supplies used in health programming based in a church or community center, among others. Community members value the impact of larger research projects. However, the impacts are not immediately visible. Small projects in response to community requests will go a long way in building trust and facilitating ongoing collaborations.

Accordingly, the CEDC will offer small grants up to $2,000 per award and up to five one-year awards annually under the Community Partnership Grant program. Community-based organizations in East Side ZIP codes are eligible to apply. We will circulate information about this opportunity through neighborhood churches, community centers, block clubs and the Buffalo Center for Health Equity, which has broad reach to Buffalo community groups. We will hold informational sessions with community organizations. For example, Project REACH (Stan Martin, Buffalo Office Director, CEDC Co-I) holds regular meetings and small events reaching community groups and members.



Figure D2. Flow chart of solicitation, review, and support for Community Partnership Grants

Applications will be accepted on a rolling basis. The application process is designed to be simple and straightforward with appropriate oversight and accountability. The applicant will write and submit a two-page application indicating applicant name, address, title of project, and a description of the project, including background, goal, activity to be conducted, expected outcomes and how the project will directly benefit the community. Additionally, a budget justification will be required to describe how the funds will be used. CEDC faculty will be available to assist community groups in writing their applications.

A review committee composed of three community members and three faculty will review proposals based on potential impact and benefit to the community, feasibility and alignment with Center of Excellence goals for community engagement. The review committee will decide whether to invite the leader(s) to meet in-person to discuss. Options include funding the proposal, recommending revisions and re-review or deciding against funding.

Funded projects will be assigned a faculty coach/advisor whose interest and experience align with the project. The coach will communicate regularly with the leaders, serve as a liaison to the Center of Excellence, advise as needed to optimize success and report back to CEDC leadership. At a minimum, the project leader(s) will check-in with the coach/advisor every three months for updates and to troubleshoot any obstacles. A one-page interim report will be submitted to the CEDC summarizing progress, obstacles, the budget, plans for the next six months and any other pertinent issues. A two-page final report with similar subheadings will be submitted at the end of the project. This report will be used to disseminate efforts, reference for future requests from the organization, help assess the Community Partnership Grant program and inform changes to enhance quality and impact.

D5. CEDC Leadership Team

Our approach to CBPR is informed by the PAR paradigm. The CEDC team was assembled because of the individual member's unique experiences engaging in the community and with praxis. Members of the team were selected because of their knowledge of Buffalo and a broader understanding of the nexus between health inequities and African American experiences with institutional barriers to community empowerment. Each member of the team offers complementary insights about building CBPR capacity (Aim 1) and the use of community organizing techniques to promote sustainable community- and system-level- change (Aim 2).

- **Robert Silverman PhD**, Core Director, Professor of Urban and Regional Planning. Professor Silverman is an internationally regarded urban planning scholar whose work focuses on community development, affordable housing, and education policy. He has worked closely with Buffalo East Side communities since he joined the UB faculty in 2003.
- **Stan Martin MM**, Co-Director, Buffalo Office Director and Senior Trainer at Ciccatelli Associates Inc. He directs the Racial and Ethnic Approaches to Community Health (REACH) program funded by the CDC. that focuses on the promotion of tobacco-free living, improved nutrition and community support for breastfeeding, and increased access to health care in Buffalo East Side neighborhoods. His group holds frequent community events, workshops, and informational sessions with community members.
- **Heather Orom PhD**, Associate Professor of Community Health and Health Behavior and Associate Dean for Equity, Diversity and Inclusion in the School of Public Health and Health Professions. Her research focuses on the causes of health disparities with a particular interest in how discrimination influences health outcomes.
- **Christopher St. Vil PhD**, Associate Professor in the School of Social Work. He is an expert on trauma and victims of violent injury, masculinity and health, gun violence, risk-taking attitudes and social welfare inequities in African American communities.
- **Henry Taylor PhD**, Professor of Urban and Regional Planning in the School of Architecture and Planning and Founding Director of the Center for Urban Studies. He is a national authority in the area of distressed urban neighborhoods and race and class issues among people of color. He recently published a landmark report on the state of Black Buffalo that has generated extensive discussion and planning among community stakeholders.
- **Susan Grinslade PhD RN** is a Clinical Professor in the School of Nursing and Fellow in the National Academy of Nursing with expertise in public health nursing and a passion for health equity. She played a key leadership role in launching the Million Hearts Initiative in Buffalo (a CDC program to reduce heart disease) facilitating the current close partnership between UB and the African American East Side communities in its earliest stages.
- **Kelly Wofford MS**, Director, Health Equity Office, Erie County Department of Health. Before joining the Erie County Department of Health, she was the Community Engagement Coordinator of the UB School of Nursing and the Director of Community Relations for the Erie County Medical Center.

D6. Summary and Five-Year Vision

The CEDC of our Center of Excellence is guided by the *participatory action research paradigm,* which focuses on linking community-based research to community organizing activities. We will train and mentor early career scholars to perform research using the principles of CBPR, in which the community guides the research agenda, participate as active partners in planning the study from the outset, are part of the research team, and benefit from the results of the research. Our strong partnerships with the community are the foundation on which the CEDC will grow. A priority of our Center of Excellence is that our research will translate into sustainable community and system-level changes. Our active collaborations with city (Mayor's office), county (County Executive), state (State Senate) and federal (Congressmember) governments with a history of working with each (see letters), position us to influence legislation and policies guided by research results that develop and assess effective approaches to impact health disparities and SDOH. Our five-year vision is that the support and impact of the Center of Excellence will catalyze a transformation of our community-based research by expanding our research workforce, training future leaders in the field, and creating a culture change by influencing researchers within and outside the Center of Excellence to design research to address root causes of health inequities and work toward translating findings into sustainable, system-level changes.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	○ Yes ● No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	○ Yes ● No
Is the Project Exempt from Federal regulations?	○ Yes ○ No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

5. APPLICANT INFORMATION **UEI*:** LMCJKRFW5R81

Legal Name*: The Research Foundation for SUNY on behalf of U. at Buffalo
Department: Sponsored Projects Services
Division:
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567

Person to be contacted on matters involving this application

Prefix:	First Name*:	Middle Name:	Last Name*:	Suffix:
	Amy		Lagowski	

Position/Title: Agreement Administartor
Street1*: The UB Commons
Street2: 520 Lee Entrance, Suite 211
City*: Amherst
County: Erie
State*: NY: New York
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 14228-2567
Phone Number*: 716-645-4419 Fax Number: Email: amy.lagowski@buffalo.edu

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): Private, Non-profit
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Igniting Hope in Buffalo New York communities: Training the Next Generation of Health Equity Researchers

12. PROPOSED PROJECT

Start Date*	Ending Date*
04/01/2024	03/31/2029

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Research Foundation for SUNY on behalf of U. at Buffalo
UEI:	LMCJKRFW5R81
Street1*:	The UB Commons
Street2:	520 Lee Entrance, Suite 211
City*:	Amherst
County:	Erie
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14228-2567
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB Clinical and Translational Research Center
UEI:	
Street1*:	875 Ellicott Street
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14203-1034
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB Jacobs School of Medicine and Biomedical Sciences
UEI:	LMCJKRFW5R81
Street1*:	955 Main Street
Street2:	
City*:	Buffalo
County:	Erie
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14203-1034
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB School of Public Health and Health Professions
UEI:	
Street1*:	3435 Main Street
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14214-3099
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 4

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	UB School of Nursing
UEI:	
Street1*:	3435 Main Street- Wende Hall
Street2:	
City*:	Buffalo
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	14214-3010
Project/Performance Site Congressional District*:	NY-026

Project/Performance Site Location 5

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB School of Architecture and Planning
UEI:
Street1*: 3435 Main Street- Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-3015
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 6

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: UB Community Health Equity Research Institute
UEI:
Street1*: 875 Ellicott Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1070
Project/Performance Site Congressional District*: NY-026

Project/Performance Site Location 7

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Buffalo Center for Health Equity
UEI:
Street1*: 257 West Genesee Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14202-2657
Project/Performance Site Congressional District*: NY-026

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Abstract_IDCϕ. f
8. Project Narrative*	
9. Bibliography & References Cited	Bibliography_Investigator_Developmentϕ. f
10.Facilities & Other Resources	
11.Equipment	

Tracking Number: GRANT13951079
Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

The University at Buffalo (UB) NIMHD Center of Excellence in Investigator Development and Community Engagement will provide well-coordinated, careful mentoring, didactic training, and professional development individually tailored to each scholar's needs. The education and training components of the Center of Excellence will fill a critical gap in our minority health and health disparities research environment by bringing comprehensive and rigorous training and mentoring in the discipline. This Center of Excellence will be the only formal training program in minority health and health disparities research at UB, bringing an enormously important resource to our training environment. The Center of Excellence will function as a centralized training center bringing coordination and communication to this key element of advancing health disparities research locally and nationally. The Investigator Development Core (IDC) will attract, mentor and train early-career investigators from a broad range of disciplines in transdisciplinary research in minority health and health disparities, including offering the opportunity to apply for pilot studies awards addressing health inequities and social determinants of health in the Buffalo region (Aim 1). Two of the most important elements for early-stage investigators to successfully establish their own independent research program are 1) training and mentoring, and 2) funding to support the development of preliminary results to be competitive for larger extramural grants. Our IDC is designed with these goals in mind. Because of lack of diversity in the health disparities research workforce, many researchers lack the insight that lived experiences bring to understanding systemic racism and the effects of discrimination and their impact on health disparities. A diverse workforce is more successful in engaging people from underrepresented groups in research and relevant stakeholders in policy making. Research related to racism and discrimination requires a multidisciplinary, broadly engaged, team science approach, which merges team science and community engagement. With this in mind, we will implement a diversity, equity, inclusion, and accessibility (DEIA) Action Plan and leverage the resources and expertise of the proposed Center of Excellence to increase and diversify our workforce, especially in health disparities research (Aim 2). Our IDC will provide expert training and mentoring in rigorous research design, methodology, statistical analysis, and community-based participatory research to early-career investigators to support their research and advance their careers in minority health and health disparities research (Aim 3). One theme of our Center of Excellence is integration of community throughout. We will assist early-career researchers in engaging community members on their research team and/or as a member of their mentoring team. Our vision for the next five years is that our Center of Excellence will facilitate the training of a more diverse faculty from more disciplines to perform innovative research in minority health and health disparities to advance their careers to independence and to create systemic change to reduce health inequities in Buffalo and beyond.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: First Name*: Oscar Middle Name Last Name*: Gómez Suffix: Ph.D

Position/Title*: Associate Professor and Division Chief
Organization Name*: SUNY at Buffalo
Department: Pediatrics
Division: Jacobs School of Medicine & Biomedical Sciences
Street1*: 1001 Main Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14203-1009

Phone Number*: (716) 323-0150 Fax Number:

E-Mail*: oscargom@buffalo.edu

Credential, e.g., agency login: GOMEZOSCAR

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD and MD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Rev. First Name*: Kinzer Middle Name Last Name*: Pointer Suffix:

Position/Title*:
Organization Name*: Concerned Clergy Coalition of Western New York
Department:
Division:
Street1*: 347 Peckham Street
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14206-1716

Phone Number*: 716-563-1609 Fax Number:

E-Mail*: kinzerpo@buffalo.edu

Credential, e.g., agency login: KINZERPO

Project Role*: Other (Specify) Other Project Role Category: Co-Director of Investigator Dev. Core

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Gregory Middle Name Last Name*: Wilding Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department: Biostatistics
Division: School of Public Health and Health Professions
Street1*: 719 Kimball Tower
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8028

Phone Number*: (716) 829-2594 Fax Number:

E-Mail*: gwilding@buffalo.edu

Credential, e.g., agency login: gewilding

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Ekaterina Middle Name Last Name*: Noyes Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department: Surgery
Division:
Street1*: 270C Farber Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8001

Phone Number*: (716) 829-5386 Fax Number:

E-Mail*: enoyes@buffalo.edu

Credential, e.g., agency login: Knoyes17

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: First Name*: Henry Middle Name Louis Last Name*: Taylor Suffix: Ph.D

Position/Title*: Professor
Organization Name*: SUNY at Buffalo
Department:
Division:
Street1*: 330A Hayes Hall
Street2:
City*: Buffalo
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 14214-8030

Phone Number*: (716) 829-5458 Fax Number:

E-Mail*: htaylor@buffalo.edu

Credential, e.g., agency login: HLTAYLOR

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: Degree Year:

Attach Biographical Sketch*: File Name:

Attach Current & Pending Support: File Name:

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Oscar		Gomez	Ph.D	Co-investigator	129,381.00	1.0			8,838.00	5,784.00	14,622.00
2.		Gregory		Wilding	Ph.D	Co-investigator	212,100.00	0.6			5,303.00	3,471.00	8,774.00
3.		Ekatarina		Noyes	Ph.D	Co-investigator	212,100.00	0.6			5,303.00	3,471.00	8,774.00
4.	Rev.	Kinzer		Pointer		Collaborator	15,606.00	1.2			6,242.00	2,559.00	8,801.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **40,971.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**40,971.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other: Pilot Studies		300,000.00
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**300,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2024 **End Date*:** 03-31-2025 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Seminars	11,169.00
Total Other Direct Costs	**11,169.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**352,140.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	352,140.00	214,806.00
		Total Indirect Costs	**214,806.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**566,946.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	566,946.00

L. Budget Justification*	File Name: Budget_Justification-Investigator_Development_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Oscar		Gomez	Ph.D	Co-investigator	131,969.00	1.0			8,838.00	5,907.00	14,745.00
2.		Gregory		Wilding	Ph.D	Co-investigator	216,342.00	0.6			5,303.00	3,545.00	8,848.00
3.		Ekatarina		Noyes	Ph.D	Co-investigator	216,342.00	0.6			5,303.00	3,545.00	8,848.00
4.	Rev.	Kinzer		Pointer		Collaborator	15,918.00	1.2			6,367.00	2,642.00	9,009.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **41,450.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**41,450.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other: Pilot Studies		300,000.00
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**300,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2025 **End Date*:** 03-31-2026 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Seminars	9,122.00
Total Other Direct Costs	**9,122.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**350,572.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	350,572.00	213,849.00
		Total Indirect Costs	**213,849.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**564,421.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	564,421.00

L. Budget Justification*	File Name: Budget_Justification-Investigator_Development_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

A. Senior/Key Person

Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Oscar		Gomez	Ph.D	Co-investigator	134,608.00	1.0			8,838.00	6,035.00	14,873.00
2.	Gregory		Wilding	Ph.D	Co-investigator	220,669.00	0.6			5,303.00	3,621.00	8,924.00
3.	Ekatarina		Noyes	Ph.D	Co-investigator	220,669.00	0.6			5,303.00	3,621.00	8,924.00
4. Rev.	Kinzer		Pointer		Collaborator	16,236.00	1.2			6,495.00	2,793.00	9,288.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **42,009.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**42,009.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other: Pilot Studies		300,000.00
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**300,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2026 **End Date*:** 03-31-2027 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Seminars	6,615.00
Total Other Direct Costs	**6,615.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**348,624.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	348,624.00	212,661.00
		Total Indirect Costs	**212,661.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**561,285.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	561,285.00

L. Budget Justification*	File Name: Budget_Justification-Investigator_Development_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Oscar		Gomez	Ph.D	Co-investigator	137,300.00	1.0			8,838.00	6,035.00	14,873.00
2.		Gregory		Wilding	Ph.D	Co-investigator	225,082.00	0.6			5,303.00	3,621.00	8,924.00
3.		Ekatarina		Noyes	Ph.D	Co-investigator	225,082.00	0.6			5,303.00	3,621.00	8,924.00
4.	Rev.	Kinzer		Pointer		Collaborator	16,561.00	1.2			6,624.00	2,848.00	9,472.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **42,193.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**42,193.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

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Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other: Pilot Studies		300,000.00
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**300,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2027 **End Date*:** 03-31-2028 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Seminars	5,463.00
Total Other Direct Costs	**5,463.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**347,656.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	347,656.00	212,070.00
		Total Indirect Costs	**212,070.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**559,726.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	559,726.00

L. Budget Justification*	File Name: Budget_Justification-Investigator_Development_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 11/30/2025

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Oscar		Gomez	Ph.D	Co-investigator	140,046.00	1.0			8,838.00	6,035.00	14,873.00
2.		Gregory		Wilding	Ph.D	Co-investigator	229,584.00	0.6			5,303.00	3,621.00	8,924.00
3.		Ekatarina		Noyes	Ph.D	Co-investigator	229,584.00	0.6			5,303.00	3,621.00	8,924.00
4.	Rev.	Kinzer		Pointer		Collaborator	16,892.00	1.2			6,757.00	2,906.00	9,663.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **42,384.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	**0.00**
						Total Salary, Wages and Fringe Benefits (A+B)	**42,384.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Case 1:25-cv-10814-WGY Document 12-24 Filed 04/04/25 Page 270 of 375

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
Equipment Item		**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file		
	Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	**0.00**

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other: Pilot Studies		300,000.00
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	**300,000.00**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 5

UEI*: LMCJKRFW5R81

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: The Research Foundation for SUNY on behalf of U. at Buffalo

Start Date*: 04-01-2028 **End Date*:** 03-31-2029 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Seminars	4,283.00
Total Other Direct Costs	**4,283.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**346,667.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1. Institutional IDC Cost On Campus	61.0	346,667.00	211,466.00
		Total Indirect Costs	**211,466.00**

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**558,133.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	558,133.00

L. Budget Justification*	File Name: Budget_Justification-Investigator_Development_Core.pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Budget Justification: Investigator Development Core

A. Personnel Salaries and Wages

Senior/Key Personnel

Oscar Gomez, MD, PhD

- Director, Investigator Development Core
- Effort: 1.0 academic months (Institutional support years 1-5: 0.50 academic months)

Dr. Gomez is an Associate Professor of Pediatrics, School of Medicine and an active advocate of recruiting underrepresented minorities in medical science to training programs. He is a member of the Harold Amos Medical Faculty Development Program of The Robert Wood Johnson Foundation, first as a scholar beginning 2009, and later as an alumnus beginning in 2012. This program is dedicated to career development of underrepresented minorities in medical science in the US. He is co-investigator and associate lead of the CTSI-associated KL2-mentored research award program in which he serves as a faculty advisor for early-career scholars. He conducts studies on the epidemiology of childhood diarrhea among children in low- and middle-income countries in Latin America and studies on hepatitis C- exposure and infection among infants in Buffalo, a condition that disproportionately impacts communities that experience adverse social determinants of health.

Responsibilities:

- Lead the Investigator Development Core
- Collaborate with Administrative Core in managing pilot project award announcements
- Coordinate training and mentoring activities
- Serve on Center of Excellence Leadership Team

Pastor Kinzer Pointer, MM

- Co-Director, Investigator Development Core
- Effort: Independent Contractor

Pastor Pointer is the pastor of Liberty Missionary Baptist Church, President and CEO of Greater Buffalo United Ministries and Chair, Erie County Poverty Committee. He is a mentor in the National Medical Association and has worked for the past five years with Drs. Murphy and Gomez on the T35 training grant “Training the Next Generation of Clinician Scientists.” He co-teaches a course in the medical school with Dr. Henry Taylor, “Health in the Neighborhood,” in which students review key literature and meet with and work with community members in their neighborhoods. Pastor Pointer also serves on the Board of the Community Health Equity Research Institute.

Responsibilities

- Co-Director of Investigator Development Core (IDC)
- Provide guidance and contribution to IDC
- Provide mentorship to pilot study awardees
- Serve on Center of Excellence Steering Committee

Henry Taylor, PhD

- Co-Investigator, Investigator Development Core
- Co-Investigator, Community Engagement and Dissemination Core
- Effort as needed

Dr. Taylor is Professor of Urban and Regional Planning, School of Architecture and Planning, Director of the Center for Urban Studies; and Associate Director, UB Community Health Equity Research Institute. His areas of expertise include urban development, housing, gentrification, underdeveloped neighborhoods, shrinking cities, race and class, and U.S.-Cuba relations. His research focuses on a historical and contemporary analysis of underdeveloped urban neighborhoods, social isolation, and race and class issues among people of color, especially African Americans and Latinos. Dr. Taylor designed and conducts the *Urban Internship Program,* which creates opportunities for graduate and undergraduate students to

become involved in neighborhood redevelopment initiatives and research projects. He has trained numerous students in this program over the years. He is also the Co-leader of the CTSI Workshop series in Health Equity.

Responsibilities:

- Provide guidance and contribution to the Community Engagement and Dissemination Core
- Provide guidance and contribution to the Investigator Development Core
- Serve on Center of Excellence Steering Committee
- Serve as Center of Excellence advocate to selected pilot studies awardees
- Facilitate partnerships and collaborations in the School of Architecture and Planning
- Help identify mentors for pilot studies awardees as needed

Ekaterina Noyes, PhD, MPH

- Co-Investigator, Investigator Development Core
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Noyes is Professor and Director of the Division of Public Health Services Policy and Practice in the UB School of Public Health and Health Professions. She has broad experience in health services research with expertise in health outcomes and quality of care assessment, large administrative data analytics, comparative effectiveness, and economic evaluations in healthcare, as well as mixed methods and implementation research. She has a particular interest in rural health and associated health disparities. She builds and trains interdisciplinary teams supported by a variety of federal and private sources including the NIH, PCORI, National Multiple Sclerosis Society, among others. Dr. Noyes is Co-PI of a K12 training grant focused on training in implementation science (K12HL138052) and Director of the Team Science and Workforce Development Cores of the CTSI.

Responsibilities:

- Provide guidance and contribution to the Investigator Development Core
- Serve as Center of Excellence advocate to selected pilot studies awardees
- Help identify mentors for pilot studies awardees as needed
- Facilitate partnerships and collaborations in the School of Public Health and Health Professions
- Connect pilot studies awardees with CTSI educational and training opportunities

Gregory Wilding, PhD

- Co- Investigator, Investigator Development Core
- Effort: 0.60 calendar months (Institutional support years 1-5: 0.30 calendar months)

Dr. Wilding is Professor of Biostatistics in the School of Public Health and Health Professions and Director of the Biostatistics, Epidemiology, and Research Design (BERD) Core of the CTSI. He has over 230 papers in peer-reviewed clinical and statistical journals and has presented his work nationally and internationally. He is skilled in a vast array of statistical analysis techniques and computer programming languages. His biostatistical interests are in the areas of clinical trials, computationally intensive methods, and tests for and measures of independence. He designed and launched the highly successful *inter Instit te or iostatisti s* for undergraduate students to attract talented and interested students into the field of biostatistics.

Responsibilities:

- Provide guidance and contribution to the Investigator Development Core
- Provide study guidance in design, biostatistical and data management to pilot studies awardees
- Link researchers with biostatistics faculty with appropriate expertise to serve as collaborators on pilot projects and subsequent larger projects.

Other Direct Costs

Pilot Studies $300,000/year

Funds are requested for pilot studies for early-career investigators. Pilot studies awards will be up to $50,000 per year for up to two years as outlined in detail in the proposal.

Seminar expenses $7,500/year

Funds are requested to conduct a monthly seminar series. We will invite national experts in minority health and health disparities for some seminars and local experts for others.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		2. 0,. . hu .
Section B, Otmer Personnel		. u .
Total Nbg der Otmer Personnel	.	
Total Salary, Waf es an+ Frinf e Beneqts (ApB)		2. 0,. . hu .
Section C, Evbi7g ent		. u .
Section D, Tra6el		. u .
1. Domestic	. u .	
2uForeif n	. u .	
Section E, Partici7ant/Trainee Sb77ort Costs		1,5. . ,. . . u .
1uTbition/Fees/HealtmInsbrance	0.00	
2uSti7en+s	. u .	
3uTra6el	. u .	
4uSbdsistence	. u .	
5uOtmer	1,5. . ,. . . u .	
9uNbg der oqPartici7ants/Trainees	.	
Section F, Otmer Direct Costs		39,952u .
1uMaterials an+ Sb77lies	. u .	
2uPbdlication Costs	. u .	
3uConsbltant Ser6ices	. u .	
4uADP/Cog 7bter Ser6ices	. u .	
5uSbdawar+s/Consortibg /Contractbal Costs	. u .	
9uEvbi7g ent or Facility Rental/User Fees	. u .	
huAlterations an+ Reno6ations	. u .	
8uOtmer 1	39,952u .	
0uOtmer 2	. u .	
1. uOtmer 3	. u .	
11uOtmer 4	. u .	
12uOtmer 5	. u .	
13uOtmer 9	. u .	
14uOtmer h	. u .	
15uOtmer 8	. u .	
19uOtmer 0	. u .	
1huOtmer 1.	. u .	
Section G, Direct Costs (A tmrb F)		1,h45,950u .
Section H, In+irect Costs		1,. 94,852u .

Section I, Total Direct an+ In+irect Costs (G p H)	2,81. ,511u .
Section J, Fee	. u .
Section K, Total Direct an+ Fee (I p J)	2,81. ,511u .

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 01/31/2026

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period *Anticipated Amount ($) *Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ○ Yes ● No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

5. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

6. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS gC8 Research Plan

5D B Number: 9C2V-9991
Expiration Oate: 91/g1/2927

Introduction

1. Introduction to Application
(for Resubmission and Revision applications)

Research Plan Section

2. Specific Aims	Aims_Inv_Oev_3ore.pdf
g. Research Stratey*0	Inv_Oev_3ore_Research_Stratey*.pdf
4. Proyress Report Publication List	

5ther Research Plan Section

V. 6ertebrate Animals

7. Select Ayent Research

M D ultiple PO/PI Leadership Plan

8. 3onsortium/3ontractual Arranyements

C. Letters of Support

19. Resource Shariny Plan(s)

11. 5ther Plan(s)

12. Authentication of Ke* Bioloyical and/or 3hemical Resources

Appendix

1g. Appendix

C. Investigator Development Core

C1. Specific Aims

Social determinants of health (SDOH) and racially informed policies dramatically affect health outcomes among people of color, including life expectancy and quality of life resulting from chronic diseases (see Overall). Advances in biomedical sciences and health interventions dramatically increased in recent decades; unfortunately, these advances do not reach underserved populations, including East Side neighborhoods in Buffalo. Understanding the root causes of health disparities in Buffalo and the complexity of factors involved, requires the training of a new generation of scholars to lead research in minority health and health disparities and achieve changes in policies and institutional structures to address and eliminate health disparities. Researchers who are new to the field face multiple challenges. Because of lack of diversity in the research workforce, many researchers lack the insight lived experiences bring to understanding systemic racism and the effects of discrimination and their impact on health disparities. A diverse workforce is more successful in engaging people from underrepresented groups in research and relevant stakeholders in policy making. Research related to racism and discrimination requires a multidisciplinary, broadly engaged, team science approach, which merges team science and community engagement (1).

While UB has faculty in a broad range of disciplines who perform research related to health disparities, there is an urgent need to train a new generation of researchers to address the multiple dimensions of health disparities in the region. The Investigator Development Core (IDC) will prepare early-stage investigators, including junior faculty and postdoctoral fellows, with the skills, support, training and mentoring to conduct research in minority health and health disparities (**Figure C1**). Our NIMHD Center of Excellence in Investigator Development and Community Engagement (Center of Excellence) will support and encourage research in populations experiencing health disparities, including racial and ethnic minorities, people with low socioeconomic status, underserved rural communities and sexual and gender minority communities. Because of the disturbing health disparities in Buffalo, a majority minority city, we place special emphasis on the structural and institutional racism accounting for adverse social determinants of health (SDOH) leading to health inequities in people of color in the Buffalo area. The tools and approaches our researchers develop in Buffalo will apply to other racially segregated cities as well.

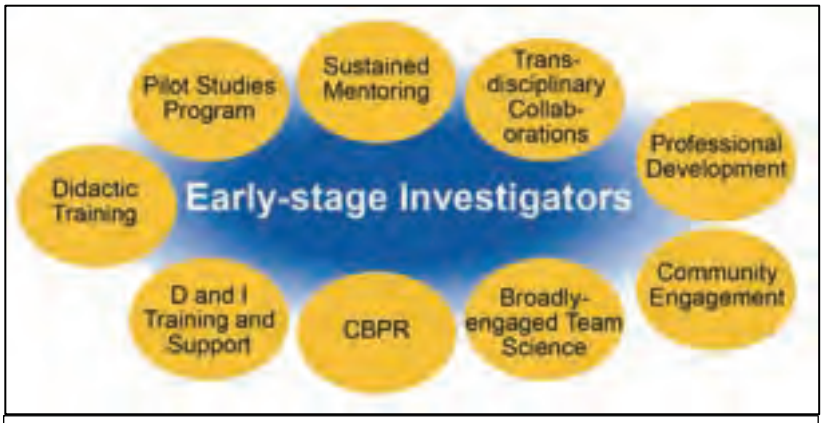


Figure C1. Overview of investigator development, training, mentoring, and support. D and I: dissemination and implementation; CBPR: community-based participatory research

Two of the most important elements for early-stage investigators to successfully establish their own independent research program are 1) training and mentoring and 2) funding to support the development of preliminary results to be competitive for larger extramural grants. Our Investigator Development Core (IDC) is designed with these goals in mind.

The IDC will support and develop early-stage investigators with a goal of nurturing independent investigators supported by extramural NIH or similar funding (e.g., Patient-Centered Outcomes Research Institute (PCORI), National Science Foundation (NSF), etc.). We will work with the Community Engagement and Dissemination Core to guide early-stage investigators in developing multidisciplinary collaborations between researchers, practice settings and diverse communities. To accomplish these goals, we propose the following specific aims:

Aim 1. Attract, mentor and train early career investigators from a broad range of disciplines in transdisciplinary research in minority health and health disparities, including offering the opportunity to apply for pilot studies awards addressing health inequities and social determinants of health in the Buffalo region.

Aim 2. Implement a diversity, equity, inclusion, and accessibility (DEIA) Action Plan and leverage the resources and expertise of the proposed Center of Excellence to increase and diversify our workforce, especially in health disparities research.

Aim 3. Provide expert training and mentoring in rigorous research design, methodology, statistical analysis and community-based participatory research to early-career investigators to support their research and advance their careers in minority health and health disparities research.

C2. Significance

Research on health disparities has grown exponentially since the 1960s, yet this expansion is not matched by an associated level of progress (2). This contradiction may be due, in part, to the limited number of health disparity researchers to address the overwhelming issues of health disparities, social justice, and structural racism in the US (3). Similarly, there is low racial and ethnic diversity in US universities among faculty, including early-stage investigators, with only 3% identifying themselves as Black or Hispanic (4). Increasing the number of investigators from underrepresented minority groups may have a positive impact on research addressing the health disparities associated with poor health indicators affecting minorities and low-income families in the US (5). Few mentoring programs address the needs of underrepresented, racially/ethnically diverse junior faculty conducting health-related research in the US (6, 7). There is an urgent need for programs to train early-career investigators in minority health and health disparities research.

C3. Innovation

Integration of the community with all phases of training. One theme of our Center of Excellence is integration of community throughout. Pastor Kinzer Pointer, an influential community leader, teacher, and mentor in the National Medical Association, is Associate Director of this Investigator Core (IDC). We will assist early career researchers who are invited to submit a full proposal for pilot studies funding in engaging a community member on their research team and/or as a member of their mentoring team.

Close affiliation with resources of the Clinical and Translational Science Institute (CTSI). The Center of Excellence and CTSI share leadership. Several faculty with effort on this proposal also have effort on the CTSA grant. The CTSI offers an extensive range of support services that are available at no cost to UB faculty and researchers. Indeed, the CTSI prioritizes supporting early-career researchers. Early-career scientists supported by the Center of Excellence are invited to join the Community of Scholars, which includes the CTSI K scholars and other “K-like scholars” in the university. The Community of Scholars is a collegial body of junior scientists who meet regularly, grow academically, broaden their professional networks, and get involved in community outreach activities.

Multidisciplinary early career researchers and mentors. Elimination of health disparities will require addressing all the SDOH, including those outside of healthcare disciplines. The leadership of the IDC represents broad expertise and backgrounds. The structure of the Center of Excellence being embedded in a university-wide institute is ideally designed to engage early-stage researchers and mentors from all 12 UB schools that encompass a broad range of relevant disciplines (see Figure B1 in Administrative Core).

Innovative DEIA action plan. As part of our commitment to better recruit, support, and retain diverse faculty, staff and trainees in academic medicine, we will implement a Diversity, Equity, Inclusion, and Accessibility (DEIA) Action Plan for all faculty, staff, trainees, and mentors in the Center of Excellence. The plan requires action by every member and each action has a follow-up, enabling accountability. This approach is showing early results in changing the culture to overcome longstanding systemic barriers to diversifying the workforce and enhancing inclusion in healthcare and research institutions (8).

Leveraging an institutional faculty hiring initiative to diversify faculty. The exceptional hiring initiative in progress at UB is a potentially powerful opportunity to enhance the diversity of our faculty and to recruit more faculty whose work interfaces with health disparities. We developed strategies for faculty in the Center of Excellence and the UB Health Equity Institute to take active roles and influence recruitments.

Mentoring and training plans tailored to each scholar. A mentoring and training plan will be tailored for each early-stage investigator supported by the Center of Excellence to be responsive to the diverse backgrounds and strengths of each scholar. An IDC faculty advocate will be assigned and will work with the scholar to develop the plan, which will include a balance of one-on-one mentoring, peer mentoring, didactic training, and professional development.

C4. Action Plan for Aims

C4.1. Action Plan for Aim 1.

Aim 1. Attract, mentor, and train early-career investigators from a broad range of disciplines in transdisciplinary research in minority health and health disparities, including offering the opportunity to apply for pilot studies awards addressing of health inequities and social determinants of health in the Buffalo region.

To expand the pool of and train early-career investigators, the IDC will offer 1) pilot studies awards with funding for one to two years (maximum award $50,000 annually); 2) comprehensive support in designing and writing the pilot studies proposals; 3) facilitation with community partners to collaborate on the project; 4) access to research resources, facilitated by close partnership with the CTSI; 5) mentoring to support awardees to ensure successful completion of projects to publication of results and submission of subsequent grant applications; 6) regulatory oversight and support to comply with applicable policies, rules and guidelines; 7) development of a dissemination and implementation plan and 8) didactic training, including lectures and workshops in minority health and health disparities research tailored to individual pilot studies awardees.

Application for Pilot Studies. This section addresses processes to apply for pilot awards. This two-tiered process is guided by our experience with the UB CTSI Translational Pilot Studies Program, which has an ~12:1 return on investment in extramural funding and successfully facilitated first national funding for a substantial number of early-stage investigators (**Figure C2**).



Figure C2. Flow chart for pilot studies program

- **Community discussions.** In collaboration with the Community Engagement and Dissemination Core, a discussion of community priorities will inform the content of the Request for Proposals (RFP) each year. The overall focus on health disparities and review priorities will remain constant. Community conversations each year will provide guidance on whether we will solicit and prioritize proposals with a particular emphasis, for example, a SDOH, based on community input. The Community Advisory Board will consider community priorities in their quarterly meeting that is scheduled in advance of the release of the RFP each year. In addition, community priorities are a continuous topic of discussion at the monthly meetings of African American Health Equity Task Force (Task Force). This group will be asked specifically to consider priorities during the meeting preceding RFP release.
- **Request for Proposals.** The opportunity to apply for pilot studies awards will be announced annually through email, website postings, social media, direct communication to all UB school leaders and our community dissemination networks. UB has effective communication channels to reach faculty and postdoctoral fellows in all 12 UB schools.
- **Letters of intent (LOIs)**. The one-page LOI will include a summary of the project, which must address minority health and/or health disparities; how the award will lead to subsequent funding; and how the project will be a step on a pathway to sustainable, community- and system-level changes. Based on review by a panel of university and community-based reviewers, eight to 12 LOIs will be invited to submit full proposals.
- **Invite full proposals for Pilot Studies**. The proposal (four-page limit) will include Specific Aims, Background and Significance and Approach, in addition to a study timeline, the role of the pilot study in securing extramural funding for a larger project and a path to a sustainable community-level change. The proposal must provide information of community member inclusion as a mentor and/or as a research collaborator.

Eligibility criteria. Early-career investigators with appointments at UB are eligible to apply. We use the NIH definition, which is an investigator who completed their terminal research degree or end of post-graduate clinical training (whichever date is later) within the past 10 years and who has not previously competed successfully as a PI for a substantial, NIH independent research award. Clinical and basic science postdoctoral fellows are also eligible and will be encouraged to apply.

Pool of applicants. A large pool of early-stage investigators and postdoctoral fellows represent our applicant pool for pilot studies and associated training and mentoring.

Table C1 shows the pool in the six health sciences schools using these criteria. Note that many additional eligible applicants are based in the other six UB schools as well (architecture and planning, arts and sciences, law, education, engineering, management). Each school has a subset of investigators whose work relates to SDOH in a broad range of domains of influence and levels of influence aligning with the NIMHD Research Framework, creating a large and diverse pool of applicants. We will actively recruit applicants who are underrepresented in science (see below).

Table C1. Applicant pool of early-stage investigators* and postdoctoral fellows in UB health sciences schools

Health Science School	Assistant Professors*	Postdoctoral Fellows
Jacobs School of Medicine and Biomedical Sciences	40	83
School of Public Health and Health Professions	8	8
School of Pharmacy and Pharmaceutical Sciences	4	23
School of Nursing	3	2
School of Dental Medicine	7	13
School of Social Work	3	1
Total	**65**	**130**

*Early career investigators defined by NIH criteria

Application materials

- Proposal described above
- A current NIH-style Biosketch for each Investigator. The personal statements should make clear the role of each investigator on the project and describe their interest in health disparities research, including past experience, academic training, current academic work, and short- and long-term goals.
- Letters of Support from mentor and community partner(s) outlining their commitment to the study.
- Budget and Budget Justification. The maximum allowable budget is $50,000 total for one year. We anticipate many awards will be ~$50,000. Applicants may apply for one or two-year awards. Funds for pilot projects must follow the Uniform Guidance Cost Principles and comply fully with applicable federal policies, rules, and guidelines for research involving human subjects and vertebrate animals.

Review process of full applications. After conflicts of interest are disclosed, LOIs will be reviewed by the Investigator Development Core (IDC) Team. We will invite approximately twice as many full proposals as we intend to fund. Requiring an LOI increases efficiency for faculty, their support staff and reviewers in ensuring that projects align with our priorities and criteria before many hours go into preparing and reviewing proposals that will be unsuccessful.

Full proposals will undergo peer scientific review by two UB faculty with expertise in areas of health equity based on the content of the proposal. The applications will be rated using the following criteria: 1) Scientific merit and innovation; 2) Significance to the field; 3) Potential impact on health equity; 4) Potential for leading to sustainable systemic changes; 5) Integration of community involvement in the project; 6) Potential for securing extramural funding; 7) Potential for creating a path to independence for the PI and8) Realistic milestones and feasibility of completion within the time frame requested. We will prioritize projects using approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities.

The IDC Team will provide the second level of review based on the scientific peer reviews and Center of Excellence priorities. This review will place emphasis on authentic engagement of community partners, potential for larger extramural funding and potential for sustainable change. Careful review and adjustment of proposed budgets presents an opportunity to ensure that requested expenses are allowable and are critical to successful completion of the project, potentially freeing up funds for additional awards.

C4.2 Action Plan for Aim 2

Aim 2. Implement a diversity equity, inclusion, and accessibility (DEIA) Action Plan and leverage the resources and expertise of the proposed Center of Excellence to increase and diversify our workforce, especially in health disparities research.

Current environment and strengths. Research teams with greater diversity in perspective, lived experience, race, ethnicity and field of study increases creativity and innovation, which leads to results with greater impact (9-12). Diversifying the workforce is critical to expand the scope and creativity of work to solve the complex

problem of health inequities. Indeed, culture change is needed to enhance recruitment and retention of people from diverse backgrounds in research settings (13, 14). Following the designation of UB as a flagship university of the SUNY system in 2022, New York State made a historic investment to grow the ranks of tenure-track faculty. In a transformational initiative, UB will be hiring ~200 new tenure-track faculty over the next couple of years (see UB President and Provost letter). In 2020, UB committed to doubling the number of faculty from historically underrepresented backgrounds by 2025. As signs of early progress, while 10% of faculty hires in 2019 were underrepresented minority, the rate steadily increased to more than 25% in 2022. During the last two years, UB recruited new Deans of four of the six Health Sciences Schools. Two are women (medicine and nursing) and the others are African American (social work) and Latinx (dental medicine). All faculty involved in this proposal are actively involved in the UB hiring initiative in their respective departments and schools. We have developed strategies for our Center of Excellence to leverage this hiring initiative to attract new faculty with interest and expertise in health disparities research and to increase the diversity of our faculty.

As part of our underlying theme of prioritizing health equity at our university, we are committed to training a workforce prepared to confront the structural racism that generated centuries of disparate health outcomes. A critical element to achieving diversity at the faculty level is establishing early pathways to science careers in groups underrepresented in science and medicine. The student population in Buffalo Public Schools, the second largest school district in the state, is 80% underrepresented minority and has one of the lowest high school graduation rates in the state. UB has placed a priority on developing career pathways beginning with elementary schools in Buffalo Public Schools through the faculty level (**Figure C3**).

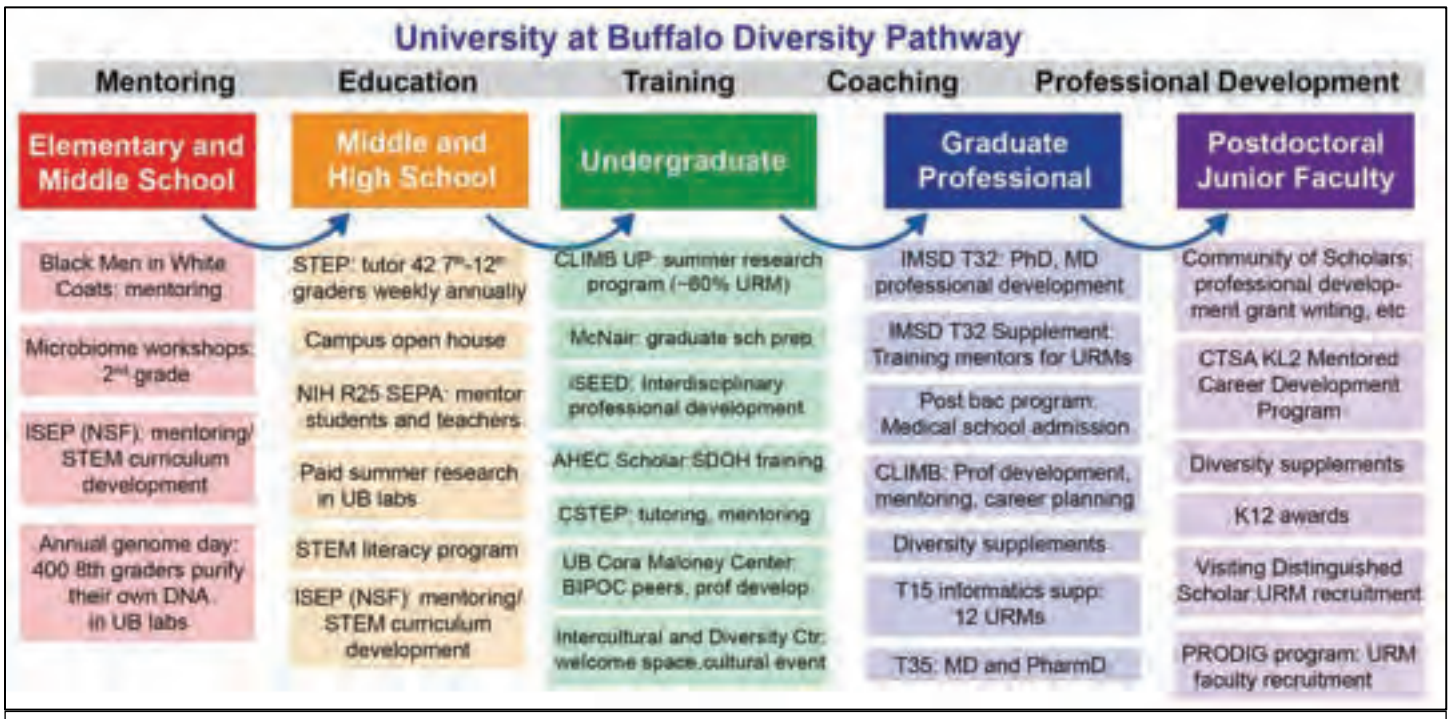


Figure C3. Selected programs in progress at UB to expand and diversify the health sciences and healthcare workforce.

Outcomes of three programs at the graduate/professional and early career faculty levels, are described:

- The **Collaborative Learning and Integrated Mentoring in the Bioscience (CLIMB)** Program, founded in 2009, offers research opportunities, mentoring, and professional development workshops to undergraduates, graduates and postdocs and has had (as of 2022) 588 participants (Current students 44% underrepresented minority [URM]). As of 2022, CLIMB UP has hosted 255 undergraduate students (68% URM) for summer internships. Of these, 103 (40%) have completed or are enrolled in PhD (28), MD (26), MD/PhD (3), Masters (13), DDS (9), PharmD (13), MPH (7), and other (4) programs. Overall, 37 are in UB programs and 66 are at other universities. The CLIMB Program has received national recognition, including the 2020 Inspiring Programs in STEM Award from Diversity Magazine.
- The **Associated Medical Schools of New York (AMSNY) Post Baccalaureate Program,** hosted by UB Jacobs School of Medicine and Biomedical Sciences, has had a substantial regional impact in expanding the pool of physicians from diverse backgrounds. UB hosts a one-year program to prepare underrepresented,

economically and educationally disadvantaged students for medical training in seven NY State medical schools that conditionally accepted them. Of 607 students (all from underrepresented or economically disadvantaged backgrounds) admitted to the program since 1991, 92% matriculated in medical school and 87% graduated. Funded by the NY State Department of Health, we enroll 20-25 students annually (4-5 per year subsequently enroll at UB). All participants attend tuition-free and receive a living stipend from AMSNY.

- **PRODiG ("Promoting Recruitment, Opportunity, Diversity, Inclusion and Growth")** is a SUNY-wide program to increase underrepresented faculty at SUNY in all disciplines and women in STEM fields. Supported by $2,199,600 in PRODiG funds since 2019, UB hired 26 new faculty, including 12 from underrepresented backgrounds (including 3 women in STEM) and 14 women in STEM fields.

In the context of this comprehensive university commitment to diversifying faculty, our Center of Excellence will strategically and intentionally contribute to recruiting faculty from groups underrepresented in science and medicine.

DEIA Action Plan. As part of our commitment to better recruit, support, and retain diverse faculty, staff and trainees in academic medicine, we will implement a Diversity, Equity, Inclusion, and Accessibility (DEIA) action plan. Institutions have a greater ability than individuals to change culture to overcome longstanding systemic barriers to diversifying the workforce in healthcare and research (12). While our Center of Excellence is not technically an institution, we will implement key elements of a DEIA Action Plan modeled after the plan of Enders et al (8), which won the 2023 JCTS Publication Award at the Association for Clinical and Translational Science (ACTS) 2023 national conference. Our plan considers multiple diversity types since individuals have several social identities that can lead to diminished respect and protection in the workplace (**Table C2**).

Table C2. Diversity Types
Race
Ethnicity
Gender identity
Cultural background
Religious tradition
Body type and size
Age
Socioeconomic background
Physical, cognitive, and social-emotional abilities
Educational level
Sexual orientation
Neurodiversity
Mental health

The plan involves intentional action with accountability by all faculty with effort on the grant (N=~11), staff (N=2), pilot studies awardees (N=20 to 25 over five years) and mentors (N=25 to 30 over five years) (**Table C3**). An awareness of one's unconscious bias is the first step in eliminating bias (15). Each person will take the Black-White Harvard Implicit Association Test and use the results to help inform their equity statement and their own actions. The results will not be shared, but rather will be used by each individual to guide their own views and actions. We will annually anonymously survey individuals who work as part of the Center of Excellence regarding their sense of belonging and inclusion (Questions like: "I feel I belong in the Center of Excellence" Strongly agree, agree etc). Each individual will create an equity statement that includes consideration of individual behaviors, activities related to their position, DEIA training and education, etc. Equity statements will be updated annually and reviewed with the IDC Core Director in the case of trainees and mentors and with the PI in the case of faculty and staff on the grant. We will give annual DEIA awards to faculty, trainees and staff to recognize noteworthy advances in promoting DEIA. We will actively engage the community in faculty and staff recruitment efforts by sharing job postings with our community partners who have extensive communication networks in Buffalo communities and include community members on search committees (with compensation). Exit interviews will be performed by Center of Excellence leadership as part of our continuous efforts to assess our culture and initiate active changes as needed to enhance the sense of inclusion and belonging for faculty, trainees and staff.

Table C3. DEIA Equity Action Plan
Assess unconscious bias
Annual anonymous survey
Equity statements
Update equity statement annually
Consider DEIA in raises and promotion recommendations to department chairs
Annual Center of Excellence DEIA Awards
Engage community in faculty and staff recruitment
Exit interviews to assess environment

This DEIA Action Plan is more than a policy statement. The plan requires action by every member of the Center of Excellence and each action has a follow-up, ensuring accountability. This DEIA Action Plan will be presented to pilot studies applicants and prospective mentors to set the expectation. We will assess the results through the annual anonymous survey, the number and impact of new initiatives that we implement from ideas in annual DEIA statements, and the demographics and characteristics of faculty, staff, pilot study awardees and trainees. The CTSI will implement the same DEIA Action Plan, emphasizing commitment to culture change.

Leveraging an Institutional Faculty Hiring Initiative to Diversify Faculty. Faculty serving on the Cores of our Center of Excellence are all influential faculty in their departments and schools (schools of medicine, nursing, public health, social work, architecture and urban planning). In addition, the Board of the UB Community Health

Equity Research Institute, in which our Center of Excellence is embedded, includes a faculty leader from each of the 12 UB schools. These faculty have significant input and participation in faculty recruitment. As part of our commitment to diversify our faculty and attract more researchers into the field of health disparities research, our Center of Excellence faculty and faculty Board members will proactively engage in faculty recruitment as part of the UB hiring initiative. They will volunteer to serve on and chair selected search committees and will reach out individually to diverse faculty candidates/colleagues in their networks and those who work in health disparities research to encourage them to apply for positions at UB to increase and diversify the pool of applicants. In conversations with junior faculty candidates with interests in health disparities research, the opportunity to apply for pilot studies and mentoring as part of the Center of Excellence is a valuable recruitment tool. When serving on search committees, our faculty will be active in ensuring an inclusive search process through suggesting proven methods, including a session on implicit bias for the search committee, and resisting the exclusion of candidates with qualifications primarily based on institutional pedigree and focus on the candidate's qualifications for the job. These experienced voices will be vocal in considering non-traditional experiences and career pathways.

Our community partners will meet with candidates of color so they may learn about the community and living in Buffalo as a person of color. These meetings have been particularly effective in recent faculty recruitments. Overall, this intentional commitment by respected faculty across multiple disciplines has strong potential for significant impact on recruiting faculty from traditionally underrepresented groups. One example of success with a recent recruit (Dr. Jamal Williams) was shown in Overall. A second recruit Dr. Gillian Franklin, who is already engaging with the Community Health Equity Research Institute and will benefit from the Center of Excellence follows. Drs. Franklin and Williams are excellent candidates to apply for pilot studies awards and train with us.

Gillian Franklin MD PhD MPH joined the Biomedical Informatics Fellowship Program at UB after having completed a postdoc in Environmental Health at the Harvard T.H. Chan School of Public Health. Her research interests focus on environmental and social determinants of health in populations that are likely to encounter health and healthcare disparities. She was appointed Assistant Professor of Biomedical Informatics (tenure track) in 2022 and was awarded a Diversity Supplement to the CTSA (UL1 TR001412-08S3). Her research project studies health literacy, with emphasis on vaccine hesitancy and developing an inferential statistical learning tool to predict individuals likely to refuse complying with public health recommendations.


Gillian Franklin
MD PhD MPH

Training mentors. Retention of faculty goes hand in hand with recruitment, particularly faculty from underrepresented groups, who have lower rates of retention than their overrepresented colleagues (16). Mentoring is critical to retention and to the success of early-career faculty investigators who form the backbone of the research workforce (7)**.** Institutional investment in a mentored research career development program for junior faculty researchers is financially sustainable and enhances participants' grant productivity over multiple years, even after completion of the training (17).

A critical element of effective mentoring is well trained mentors. Competency-based, structured research mentor training improves mentors' skills (18). It is especially important to understand and use approaches that meet the specific needs of faculty from underrepresented groups, who face unconscious bias, diversity pressures, isolation, and racism (7). A systematic review has shown that mentoring programs for minority faculty increases retention, academic productivity, and promotion rates for this group (19).

Each mentor-scholar dyad of pilot study awardee and assigned mentor will attend the mentoring workshop series conducted by the CTSI Workforce Development Core and KL2. This interactive program is designed specifically for mentor-protégé pairs and is offered annually to all faculty and trainees at UB. It includes an in-person format (five one-hour monthly sessions) (**Table C4**) and an online platform to offer resources and host forums (18, 20). Scholars and mentors attending the mentoring training will have the value of multiple viewpoints, more experience, and more feedback from these collaborations. This popular mentor training program, launched in 2016, has been revised and improved based on experience and feedback from those who have completed the program.

Table C4. Mentor-Protege Mentoring Workshop Series
Establishing and Monitoring a Mentoring Relationship
Effective Communication
Conflict Resolution in Mentoring
Creating an Inclusive Learning and Research Environment
Bringing a Mentoring Relationship to a Satisfactory End

C4.3 Action Plan for Aim 3.

Aim 3. Provide expert training and mentoring in rigorous research design, methodology, statistical analysis and community-based participatory research to early-career investigators to support their research and advance their careers in minority health and health disparities research.

Mentoring and support for pilot studies applicants and awardees. In addition to making pilot studies funding available, our proposed plan places strong emphasis on mentoring and supporting early career pilot studies applicants and awardees to maximize their likelihood of success and maximize the impact of their work on the community while advancing careers (**Table C5**). The mentoring begins while preparing proposals (see yellow boxes in **Figure C1** above). At the time of invitation to write a full proposal, our Core will work with the applicant to link them with appropriate community partners as needed. The pilot study applicant will also meet with Dr. Gregory Wilding, Professor of Biostatistics, a member of the IDC Team and expert in research design and biostatistics, to provide input as the proposal is being planned. Dr. Wilding may assign a biostatistics colleague with appropriate expertise to work with the applicant. Based on our CTSI experience, this often leads to new collaborations with biostatisticians and inclusion as co-investigators on the pilot studies, increasing the rigor of the proposal. The IDC will also work with awardees to ensure access to appropriate research resources, particularly the extensive resources through the CTSI, which are available to all UB faculty and scholars at no charge.

Table C5. Mentoring and support for pilot study applicants and awardees

Coaching session to write proposals
Training in working with community
Link with community partners
Mentor-protégé workshop series
Research design and biostatistics support
Link with relevant CTSI cores
Expert research compliance support
Assign advocate/mentor from Center of Excellence
Include community partner on each mentoring committee
Didactic training in health disparities
Join Community of Scholars
Grant writing workshops
Communication of research findings

When proposals are funded, a faculty member of the IDC Team will be assigned to each awardee to ensure an effective mentoring committee and mentoring plan are in place, assist in linking with appropriate resources, troubleshoot any obstacles and meet every two months to ensure continued progress. We anticipate most awardees (early-career assistant professors and postdocs) will have mentors and mentoring committees in their home departments. The assigned IDC Team advocate will assess the existing mentoring team to ensure that mentor(s) have appropriate expertise and experience in minority health and health disparities research. In the case that a scholar would benefit from an additional mentor(s), the IDC Team member will work with the scholar and the existing mentoring team to identify a mentor with appropriate expertise. In some cases, this may include mentors from outside UB, including other academic institutions, or in some cases, stakeholders outside of academia. Either way, the IDC Team member will serve as an advocate and facilitator as their project and career progress. Members of the IDC Team and Center of Excellence Leadership team are well connected nationally in health equity research, facilitating collaboration and mentoring opportunities beyond UB as needed. The approach is not intended to replace current mentors, but rather to complement mentoring teams to the benefit of the scholars.

Qualifications and research experience of mentoring teams. In evaluating mentor qualifications, we will use the same criteria applied to mentors of NIH training grants. Mentors will be expected to have extramural funding, a track record of successful mentoring of postdocs and early career faculty and publications in peer reviewed journals. Their research will have a focus on health disparities in the general or related domain of that of the scholar. Mentors can be faculty in any of the 12 UB schools, depending on the focus of the scholars' work, creating a large pool of qualified mentors. Mentors assigned by the Center of Excellence will undergo mentor training described in Aim 2.

Sustained mentorship. As noted above, a member of the IDC will be assigned to each pilot studies award recipient to oversee and guide career mentoring, which will proceed in cooperation with the scholars' own department-based mentoring. Mentoring teams will provide guidance for scholars to apply for extramural funding tailored to their career paths toward independence. The most likely funding pathway for assistant professors will be either individual K awards or R01s (or similar mechanisms), depending on career stage, publication record and any funding history. Postdoctoral scholars will be candidates for F32, K awards or R-like awards. We envision some scholars from this program being excellent candidates for the CTSA-linked KL2 mentored career development program, which has been highly successful in training early career faculty to become independent investigators.

Research mentoring and career guidance will continue through independence. Additional mechanisms for continued guidance include participating in the Community of Scholars, selected didactic training aligning with

the scholars' interest (**Table C6** below), access to annual grant writing workshops and regular meetings with the Center of Excellence-assigned advocate (**Figure C4**).



Figure C4. Continued mentorship of scholars. The Center of Excellence-assigned advocate/mentor follows scholar through independence for advocacy and career guidance. Scholars participate in mentor-protégé workshop (year 1) and grant writing workshop (year 2). Additional resources shown here are tailored for individual scholars working with advocate/mentor.

Pilot studies recipients will also be invited to become Research Fellows of the Health Equity Institute, which include faculty and trainees with an interest and commitment to research in health disparities. Fellows can receive assistance in developing their research ideas and grant applications, have their research papers and grant applications critiqued and participate in selected projects that align with their research and career interests. These fellows may also receive assistance in building community partnerships and developing interactive relationships with East Side neighborhood residents. The Health Equity Institute hosts an annual research day, which is an interactive event where research is shared and presented and with opportunities for new research collaborations and community partnerships.

Compliance with federal regulations and NIH policies. The Health Equity Institute Administrator will meet with each pilot study awardee and their team to review requirements, conditions of funding and to address any questions. They will together work with the UB Sponsored Projects Office to assist and ensure compliance with Federal policies, rules, and guidelines for research involving human subjects and vertebrate animals, from the pre-approval process and throughout the study. All human subjects research at UB goes through the AAHRPP-accredited UB IRB, which acts as the regional IRB through affiliation agreements with our hospital partners, Kaleida Health and Erie County Medical Center. The CTSI performs IRB pre reviews on all protocols submitted to the IRB and works with PIs to prepare protocols that follow all the required guidelines. These pre reviews reduce IRB turnaround time substantially by ensuring submission of well-prepared IRB protocols.

Training in working with the community. A priority expressed consistently by our community partners during our many planning discussions for this proposal was that early career investigators undergo training in working with communities. Many academic researchers have limited knowledge of emerging science and processes for effectively engaging communities, especially researchers who are new to working with communities (21). It is critical that our researchers recognize the community as an asset that can show them how to understand and address social determinants of health, advance trainees' ability to work hand in hand with community members, and increase the impact of their research discoveries (22, 23).

We will develop an interactive workshop series in working with communities that will be required of all pilot studies awardees and will be available to all researchers. The module will be tailored to working with communities in the Buffalo region and modeled after successful existing programs (21, 24). Community members with effort on this proposal will lead the training module with the participation of the Community Advisory Board (see Administrative Core) and with support by expert faculty on this Core and the Health Equity Institute Administrator. The training module will emphasize understanding and training in cultural humility, an orientation based on self-reflection; appreciation of community members' expertise on the social and cultural context of their lives; and willingness to share authority, credit for success and responsibility for failure (25-27). Cultural humility means admitting what one does not know and is willing to learn from community members who experience adverse social determinants of health. In addition to training in cultural humility, the workshops will include implicit bias training, consideration of the value of community engaged research, principles of CBPR, and interacting with community members.

Didactic Training in Minority Health and Health Disparities. In addition to providing mentoring, the IDC will offer a didactic research training program directed to early career investigators, including pilot studies program applicants and awardees, and make the educational offerings available widely to the UB community. We have

carefully designed a program adding value to early-stage investigators but is mindful of the importance of managing time for performing research. The program will be a combination of new training modules developed specifically as part of this proposal and leveraging rich and valuable existing educational opportunities in the UB environment, particularly those offered by the CTSI. This approach facilitates networking and collaboration opportunities for our investigators and ensures the feasibility of this plan from a budgetary perspective in that we are not launching all these educational modules from scratch. **Table C6** lists the didactic training in which pilot studies awardees will participate. We will also invite and encourage LOI and full proposal applicants whose projects were not chosen each year and other early-stage investigators to participate.

- Coaching sessions for LOIs and full proposal submission. These sessions are designed to assist investigators in becoming more successful in writing pilot studies proposals for basic biomedical, behavioral, clinical and/or population health research on diseases and conditions that disproportionately affect the health and well-being of ethnic minority and other underserved and marginalized communities (28). We will offer a session on how to write high quality LOIs and a second session on writing research proposals to the pilot research program. During these sessions, applicants will receive tips on how to make the LOI objective, focused and responsive to the RFA. Those applicants, who after submitting LOIs are invited to submit full applications, will have the opportunity to attend another session to receive tips on how to write a high-quality research proposal.

Table C6. Didactic training modules for early-stage investigators

Training Module	New or existing	Sessions per year	Hours per year
For all pilot studies awardees:			
Pilot Studies Symposium	New	1	4
Monthly seminar series	New	12	12
Annual Health Equity Institute Research Day	Existing	1	8
Igniting Hope Conference Series	Existing	1	8
LOI and Pilot Studies Coaching Sessions	New	2	2
CTSI Implementation Science Seminar series	Existing	5	5
CTSI Health Equity Workshop Series	Existing	5	7.5
CTSI Community-University Collaborations in Research	Existing	3	6
Optional, tailored to individual scholars:			
Join Community of Scholars			
Selected CTSI Core Competency workshops			
CTSI grant writing workshop			

- Implementation science seminar series. This seminar series is hosted by the CTSI. Rapid advancements in translational research have led to innovative clinical discoveries and evidence-based interventions that should be implemented in real-world settings. However, implementation of these new effective interventions into practice is often delayed. Training scholars in implementation science bridges research to practice for diverse populations to advance health equity (29). Research on the adoption and/or scaling up of innovative strategies and tools and interventions for disease prevention in communities affected by health disparities will provide key data for policy makers, and local public health authorities to implement changes that will impact social determinants of health.

- Annual Center of Excellence Pilot Studies Symposium. Pilot study awardees will present their research in oral presentations at the end of their funding period, and the most recent round of awardees will present posters of their ongoing studies, providing a venue to facilitate networking and collaborations. Dr. Oscar Gomez will give a talk on “tips for writing successful pilot studies” that will generate interest among postdocs and early career faculty. This half-day symposium will be advertised widely throughout UB and the community, bringing attention to the pilot studies and resources that the Center of Excellence offers and attracting more researchers into the discipline and more applicants for pilot studies.

- Monthly Seminar Series. This series will feature UB and community researchers, in addition to invited national experts (two per year). Visiting speakers will meet with pilot studies awardees and other early career researchers to discuss their work and to interact personally with nationally recognized experts in the field.

- Annual Health Equity Research Day. We will invite faculty, trainees, and community members to submit abstracts, that will be reviewed and invited for oral or poster presentations. This day-long event hosted by the UB Community Health Equity Research Institute features a keynote speaker, small group breakout sessions on key topics, short talks, and poster sessions. In our first two research days, presenters have been from eight of the 12 UB schools and multiple community organizations, with presentations related to indigenous, LGBTQ, and rural communities, new Americans, immigrants, and asylum seekers, in addition to

under resourced and underserved urban communities. The event is a highly interactive, multidisciplinary interactive event, indicative of broad interest in health disparities research regionally. Attendance has been 80 to 90 people each year.

- CTSI Core Competency Workshop Series in Health Equity. Each year the CTSI offers a five-workshop series on social determinants of health and health equity, run by Dr. Henry Taylor, Associate Director of the UB Community Health Equity Research Institute and Dr. Yu Ping Chang, Senior Associate Dean of the School of Nursing, and member of the Health Equity Institute Board. This series has been quite popular with approximately 60 attendees per session.
- CTSI Core Competency Workshop Series in Community-University Collaborations in Research. Each workshop consists of a diverse, community-friendly panel designed to engage the audience in discussion about perceived barriers to conducting research with communities and using innovative approaches to address health disparities in Western New York communities.
- Igniting Hope Conference Series. This regional conference supported for 3 years by an NIH conference grant (R13 TR003486) will continue to be held each year as a joint effort by the UB Community Health Equity Research Institute, the Buffalo Center for Health Equity and the CTSI. The conference is described in Overall and in our recent publication (30).

The planned didactic training is approximately 84.5 hours per year (**Table C6**). Based on a 40-hour work week, that represents 4.2% effort. This amount is not onerous but will enhance career development substantially.

Professional development. We anticipate that pilot studies awardees will be at various stages of their careers. Therefore, we will provide mentoring, expert support and didactic training tailored to their career stage and needs and will individualize professional development support.

Investigators can choose from a range of professional development opportunities, guided by discussion with their assigned IDC Team advocate/mentor.

- Community of Scholars which is part of the CTSI Mentored Career Development Program, is a collegial body of junior scientists who meet regularly, grow academically, broaden their professional networks, and get involved in community outreach activities. Dr. Gomez, Director of the IDC, is the faculty advisor of the Community of Scholars. The group has a work-in-progress series in which scholars present their work, professional development sessions to enhance opportunities to develop professional and interpersonal skills with the goal of becoming a successful and independent investigator, sessions on preparation of CVs and promotion dossiers, and others.
- CTSI Core Competency workshop series on clinical and translational research is offered each year and open to all faculty, trainees, and staff. Workshops in addition to those in **Table C6** that may be particularly relevant include Biostatistics Boot Camp, Translational Teamwork, Scientific Communication, Biomedical Informatics, and others. Each series is three to eight workshops and can be attended in full or individually.
- Workshops on grant writing are offered by a team from the CTSI and the UB Office of Research Advancement on a yearly basis to early-stage investigators. Senior faculty with strong track records in grant funding lead these workshops.
- Communication of research findings. The Community Engagement and Dissemination Core will provide training and coaching in communication of research findings, a critical skill for any researcher. Training sessions will place emphasis on oral communication skills of scientific information, having conversations with community members and community leaders, short oral presentations, and press interviews.
- Scholars will be encouraged to attend national and international meetings to present their research findings, interact with researchers in aligned fields and to establish a collaborative network. In addition, the IDC advocate and scholar will discuss joining professional and scientific organizations that would benefit the scholar's career development.

C5. IDC Leadership Team

Investigator Development Core (IDC) Leadership Team. The core will have a multidisciplinary leadership team with recognized expertise in health equity, social justice, epidemiology, medicine, and health policy. Also, each leader has extensive experience in leading training grants and/or mentoring trainees. The IDC leadership team will advise the Core Director and Associate Director and contribute to planning and oversight of

core activities, including the pilot studies awards, the training program for scholars in health disparities who are awarded pilot studies, and for community members who are participating in the pilot research projects. **Table C7** describes the diverse and valuable attributes of the members of the IDC Leadership Team.

Table C7. Attributes of the Investigator Development Core Leadership Team

Strong track record as mentors (all)
Four disciplines in three UB schools represented
Community leader and National Medical Association mentor
Three of five underrepresented in biomedical sciences
Three of five serve as faculty in CTSI cores

- **Oscar Gomez MD PhD, Core Director.** Dr. Gomez is an Associate Professor of Pediatrics, School of Medicine, and an active advocate of recruiting underrepresented minorities in medical science to training programs. He has excellent experience in leading training and mentoring programs. He is a member of the Harold Amos Medical Faculty Development Program of The Robert Wood Johnson Foundation, first as a scholar beginning 2009, and later as an alumnus beginning in 2012. This program is dedicated to career development of underrepresented minorities in medical science in the US. He is co-investigator and associate lead of the CTSI-associated KL2-mentored research award program in which he serves as a faculty advisor for early-career scholars. He has expertise in molecular epidemiology, microbial pathogenesis, and vaccine development. His research includes studies on the epidemiology of childhood diarrhea among children in low- and middle-income countries in Latin America and studies on hepatitis C- exposure and infection among infants in Buffalo, a condition that disproportionately impacts communities that experience adverse social determinants of health.
    - Dr. Gomez will oversee the IDC, working with team members and guidance from the Center of Excellence Leadership Team (see Administrative Core). He will work with the Administrative Core in managing pilot project award announcements, proposal evaluation and selection and will coordinate training activities and serve on the Center of Excellence Leadership Team.
- **Pastor Kinzer M. Pointer MM, Associate Core Director** is the Pastor of Liberty Missionary Baptist Church, President and CEO of Greater Buffalo United Ministries and Chair of the Erie County Poverty Committee. He is an active mentor in the National Medical Association and works closely with Drs. Murphy and Gomez on the T35 training grant “Training the Next Generation of Clinician Scientists.” (T35 AI089693). He co-leads an innovative course in the School of Medicine “Health in the Neighborhood.” Pastor Pointer also serves on the Board of the Community Health Equity Research Institute. As a community leader and community member he will contribute ideas and input to this core and participate in mentoring pilot studies awardees.
- **Henry-Louis Taylor Jr. PhD** is Professor of Urban and Regional Planning, School of Architecture and Planning, Director of the Center for Urban Studies; and Associate Director, UB Community Health Equity Research Institute. His areas of expertise include urban development, housing, gentrification, underdeveloped neighborhoods, shrinking cities, race and class, and U.S.-Cuba relations. His research focuses on a historical and contemporary analysis of underdeveloped urban neighborhoods, social isolation, and race and class issues among people of color, especially African Americans and Latinos. Dr. Taylor designed and runs the *Urban Internship Program,* which creates opportunities for graduate and undergraduate students to become involved in East Side neighborhood redevelopment initiatives and research projects. He is also the Co-leader of the CTSI Workshop series in Health Equity.
- **Gregory Wilding PhD,** Professor of Biostatistics and director of the Biostatistics, Epidemiology, Research Design (BERD) Core of the CTSI. He has expertise in clinical trial design, permutation tests, resampling techniques, goodness-of-fit tests, distributional characterizations, copulas, tests of independence, and biostatistics. He designed and launched the highly successful *Winter Institute in Biostatistics* for undergraduate students to attract talented and interested students into the field of biostatistics. Dr. Wilding and his team will meet with each pilot studies scholar and advise on research design and data analysis, and in many cases facilitate collaboration with a biostatistics faculty with appropriate expertise for the project.
- **Ekaterina Noyes PhD MPH,** Professor and Director of the Division of Public Health Services Policy and Practice in the UB School of Public Health and Health Professions. She has broad experience in health services research with expertise in health outcomes and quality of care assessment, large administrative

data analytics, comparative effectiveness, and economic evaluations in healthcare, as well as mixed methods and implementation research. She builds and trains interdisciplinary teams supported by a variety of federal and private sources including the NIH, PCORI, National Multiple Sclerosis Society, among others. Dr. Noyes is Co-PI of a K12 training grant focused on training in implementation science (K12HL138052) and Director of the Team Science and Workforce Development Cores of the CTSI.

The IDC Team will be assisted by a Project Manager and by the Administrator of the Community Health Equity Research Institute, whose salary is supported by the University (see President and Provost letter).

The day-to-day activities of the IDC will be managed by the Director with frequent discussion with the Associate Director and the assistance of the Institute Administrator and Project Manager. The IDC Team will meet monthly and will have active input into the conduct of the Core, including the mentoring and support of the pilot studies awardees. The IDC Director serves on the Center of Excellence Leadership Team to ensure communication and alignment of goals and activities. IDC leaders will meet monthly with Community Engagement and Dissemination Core leaders and as needed to work in concert to provide expertise on community involvement and dissemination plans for ongoing pilot studies.

C6. Summary and Vision

A Center of Excellence in Investigator Development and Community Engagement will be the only formal training program in minority health and health disparities research at UB, bringing an enormously important resource to our training environment. Our Investigator Development Core takes a comprehensive approach to training the next generation of researchers in minority health and health disparities. An important element of our approach is taking intentional action to contribute to our university's goal to increase the diversity of our faculty, leveraging the unique opportunity of a large faculty hiring initiative. Researchers from diverse backgrounds bring insight that comes with lived experiences to better understand systemic racism and discrimination and their impact on health disparities. In addition to implementing an innovative DEIA Action Plan, a strategy that is showing early signs of progress in other institutions, we propose active involvement of Center of Excellence faculty in recruitment in their departments and schools. A Center of Excellence with the opportunity for pilot studies and extensive training and mentoring will be an attractive feature in our environment for recruiting faculty candidates with interest and expertise in minority health and health disparities research.

Our goal to train and mentor early-career investigators to establish their own independent research program is responsive to their needs by providing two of the most important elements for early-stage investigators to successfully advance their careers: 1) training and mentoring and 2) funding to support the development of preliminary results to be competitive for larger extramural grants. We actively engage faculty from all 12 UB schools, which encompass a broad range of disciplines related directly to SDOH, which span beyond the health sciences. This connection with researchers in diverse disciplines gives us the opportunity to attract new researchers to perform research in health disparities. Faculty outside of the health sciences are often not aware that their work relates directly to SDOH impacting health outcomes. We view one of the roles of our Center of Excellence as to increase awareness of the breadth of health disparities research by serving as a university-wide resource. Our vision for the next five years is that our Center of Excellence will facilitate the training a more diverse faculty from more disciplines to perform innovative research in minority health and health disparities to advance their careers to independence and to create systemic change to reduce health inequities in Buffalo and beyond.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data *	● Yes ○ No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.	
Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
The form does not have any study records		

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
1	TBD Based on Pilot Study Selections	Yes	Human_Subjects.pdf

DELAYED ONSET STUDY(IES) JUSTIFICATION

Study Title:
Multiple Delayed Onset Studies: Investigator Development Core

Human subjects research is anticipated within the project period for which we are requesting funding. However, we are not able to fully define plans for human subject studies as part of this application, since the investigators and their research projects will be determined post-award.

Once funded, the University at Buffalo (UB) Center of Excellence in Investigator Development and Community Engagement Core will distribute a call for letters of intent to UB early career investigators for pilot studies related to health disparities and social determinants of health. We anticipate that some but not all the pilot studies will be clinical trials.

For the pilot studies, we assure that all policies will be followed inclusive of human subject research, multi-site studies and single IRB, and registration and dissemination of clinical trials information.

Any human subjects research conducted as part of the pilot studies program will receive approval from the UB AAHRPP-certified Institutional Review Board (IRB) and will be submitted to NIH for prior approval before initiating the proposed human subjects research.

Domestic sites of multi-site studies conducting non-exempt research involving human subjects will use a single IRB of record.

Clinical trials will be registered and results will be submitted to Clinicaltrials.gov, consistent with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.

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Exhibit D to Shurtleff Declaration

This notice has expired. Check the **NIH Guide** (https://grants.nih.gov/funding/searchguide/) for active opportunities and notices.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Heart, Lung, and Blood Institute (NHLBI (http://www.nhlbi.nih.gov/))
National Cancer Institute (NCI (https://www.cancer.gov/))
National Human Genome Research Institute (NHGRI (https://www.genome.gov/))
National Institute on Aging (NIA (http://www.nia.nih.gov/))
National Institute on Alcohol Abuse and Alcoholism (NIAAA (http://www.niaaa.nih.gov/))
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (http://www.niams.nih.gov/))
National Institute of Biomedical Imaging and Bioengineering (NIBIB (http://www.nibib.nih.gov/))
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (http://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))
National Institute on Drug Abuse (NIDA (http://www.nida.nih.gov/))
National Center for Complementary and Integrative Health (NCCIH (http://www.nccam.nih.gov/))
National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))
National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))
National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))
National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/)) - participation added for due dates on/after January 8, 2021 (see NOT-DK-21-002 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-21-002.html))

Office of Research Infrastructure Programs (ORIP (https://orip.nih.gov/))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Mentored Research Scientist Development Award (Parent K01 - Independent Clinical Trial Not Allowed)

Activity Code

K01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k01&Search.x=0&Search.y=0&Search_Type=Activity)
Research Scientist Development Award - Research & Training

Announcement Type

EXPIRED

Reissue of PA-19-126 (https://grants.nih.gov/grants/guide/pa-files/PA-19-126.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=33295) associated with this funding opportunity

April 24, 2024 - This PA has been reissued as PA-24-176 (//grants.nih.gov/grants/guide/pa-files/PA-24-176.html)

December 20, 2023 - Notice of NCIs Participation in NIH Mentored Research Scientist Development Awards (Parent K01) Notices of Funding Opportunity. See Notice NOT-CA-24-020 (//grants.nih.gov/grants/guide/notice-files/NOT-CA-24-020.html)

September 27, 2023 - Update to NIDDK Policy on Combined Support Between and Institutional Career Development Award and an Individual Career Development Award. See Notice NOT-DK-23-025 (//grants.nih.gov/grants/guide/notice-files/NOT-DK-23-025.html)

March 2, 2023 - Notice to Extend the Expiration Date for All NIH Career Development Award (K) Parent Announcements. See Notice NOT-OD-23-096 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-23-096.html)

NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

May 3, 2022 - Understanding the Basic Mechanisms of Immune-related Adverse Events (irAEs) in Cancer Immunotherapy. See Notice NOT-CA-22-063 (https://grants.nih.gov/grants/guide/notice-files/NOT-CA-22-063.html).

March 4, 2022 - NIDDK Notice of Continuation of Temporary Extension of Eligibility for the NIH Mentored Research Scientist Development Award (K01) Award During the COVID-19 Pandemic. See Notice NOT-DK-22-016 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-22-016.html).

See Notices of Special Interest (//grants.nih.gov/grants/guide/notice-files/NOT-DA-23-002.html) related to this funding opportunity

October 28, 2021 - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).

September 13, 2021 - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).

August 5, 2021 - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html).

August 5, 2021 - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)

April 20, 2021 - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)

See Notices of Special Interest (//grants.nih.gov/grants/guide/notice-files/NOT-MH-22-045.html) related to this opportunity

- **May 20, 2021** - NIDDK Notice of Continuation of Temporary Extension of Eligibility for the NIH Mentored Research Scientist Development Award (K01) Award During the COVID-19 Pandemic. See Notice NOT-DK-21-019 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-21-019.html).
- **April 26, 2021** - Guidance Regarding Reduction of Effort for Surgeons on NIA Individual Mentored K Awards. See Notice NOT-AG-21-019 (//grants.nih.gov/grants/guide/notice-files/NOT-AG-21-019.html).
- **November 17, 2020** - Temporary Extension of Eligibility for the NIDDK K01 Mentored Research Scientist Development Award During the COVID-19 Pandemic. See Notice NOT-DK-20-054 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-20-054.html).
- **November 10, 2020** - Notice of NIDDK Participation in PA-20-190 and PA-20-176. See Notice NOT-DK-21-002 (/grants/guide/notice-files/NOT-DK-21-002.html).

Funding Opportunity Announcement (FOA) Number

PA-20-190

Companion Funding Opportunity

PA-20-176 (https://grants.nih.gov/grants/guide/pa-files/PA-20-176.html) - Mentored Research Scientist Development Award (Parent K01 - Independent Clinical Trial Required)

PA-20-191 (https://grants.nih.gov/grants/guide/pa-files/PA-20-191.html) - Mentored Research Scientist Development Award (Parent K01 - Independent Basic Experimental Studies with Humans Required)

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.213; 93.172; 93.837, 93.838, 93.839, 93.840, 93.233; 93.866; 93.273; 93.855; 93.846; 93.286; 93.279; 93.173; 93.121; 93.242; 93.307; 93.361; 93.351, 93.398, 93.399, 93.393

Funding Opportunity Purpose

The purpose of the NIH Mentored Research Scientist Development Award (K01) is to provide support and protected time (three to five years) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence. Although all of the participating NIH Institutes and Centers (ICs) use this support mechanism to support career development experiences that lead to research independence, some ICs use the K01 award for individuals who propose to train in a new field or for individuals who have had a hiatus in their research career because of illness or pressing family circumstances..

This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or a separate ancillary clinical trial. Applicants to this FOA are permitted to propose research experience in a clinical trial led by a mentor or co-mentor. Applicants proposing a clinical trial or an ancillary clinical trial as lead investigator, should apply to the companion FOA (https://grants.nih.gov/grants/guide/pa-files/PA-20-176.html).

Key Dates

Posted Date

May 6, 2020

Open Date (Earliest Submission Date)

May 12, 2020

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

Standard dates (//grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply.

The first standard application due date for this FOA is June 12, 2020.

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s). Applications are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Standard AIDS dates (//grants.nih.gov/grants/guide/url_redirect.php?id=11112) apply.

The first AIDS application due date for this FOA is September 7, 2020.

All applications are due by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due the listed date(s).

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

Earliest Start Date

Standard dates (//grants.nih.gov/grants/guide/url_redirect.php?id=11113) apply

Expiration Date

New Date May 8, 2024 (Original Date: May 8, 2023) per issuance of NOT-OD-23-096 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-23-096.html)

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 1. Overview Information
Part 2. Full Text of the Announcement

- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information

Section VII. Agency Contacts
Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NIH Institutes and Centers (ICs) support a variety of mentored and non-mentored career development award programs designed to foster the transition of new investigators to research independence and to support established investigators in achieving specific objectives. Candidates should review the different career development (K) award programs to determine the best program to support their goals. More information about Career programs may be found at the NIH Extramural Training Mechanisms (//grants.nih.gov/grants/guide/url_redirect.php?id=41159) website.

The objective of the NIH Mentored Research Scientist Development Award (K01) is to provide salary and research support for a sustained period of protected time (3-5 years) for intensive research career development, under the guidance of an experienced mentor, or sponsor in the biomedical, behavioral or clinical sciences leading to research independence. The expectation is that, through this sustained period of research career development and training, awardees will launch independent research careers and become competitive for new research project grant (e.g., R01) funding.

Although all of the participating NIH Institutes and Centers (ICs) use this mechanism to support career development experiences that lead to research independence, some ICs use the K01 award for individuals who propose to train in a new field or for individuals who have had a hiatus in their research career because of illness or pressing family circumstances. Other ICs utilize the K01 award to support research in other fields.

Note: This Funding Opportunity Announcement (FOA) is designed specifically for candidates proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary study clinical trial. Under this FOA candidates are permitted to propose research experience in a clinical trial led by a mentor or co-mentor. Those proposing a clinical trial or an ancillary clinical trial as lead investigator, should apply to the companion FOA (PA-20-176 (https://grants.nih.gov/grants/guide/pa-files/PA-20-176.html)).

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective candidates are strongly encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html), to make sure that their application is appropriate for the requirements of one of the participating NIH ICs.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose a clinical trial.

Note: Applicants may propose to gain experience in a clinical trial led by a mentor/co-mentor as part of their research career development.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period may not exceed 5 years.

Other Award Budget Information

Salary

The participating NIH Institutes and Centers will provide salary and fringe benefits for the award recipient (see Table of IC-Specific Information, Requirements and Staff Contacts). (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html)
Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide. See also NOT-OD-17-094 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-094.html)

The total NIH contribution to salary, however, may not exceed the legislatively mandated salary cap. See: http://grants.nih.gov/grants/policy/salcap_summary.htm (https://grants.nih.gov/grants/policy/salcap_summary.htm).

Other Program-Related Expenses

The participating NIH Institutes and Centers will provide research development support for the award recipient.

See the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html) funds may be used for the following expenses: (a) tuition and fees related to career development; (b) research-related expenses, such as supplies, equipment and technical personnel; c) travel to research meetings or training; and (d) statistical services including personnel and computer time.

Salary for mentors, secretarial and administrative assistants, etc. is not allowed.

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs.

NIH grant policies as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- o NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.

- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

All PD(s)/PI(s) must be registered with ORCiD (https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help (https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D_____29).

Eligible Individuals (Program Director/Principal Investigator)

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her mentor and organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. Multiple PDs/PIs are not allowed.

By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

Current and former PDs/PIs on NIH research project (R01), program project (P01), center grants (P50), other major individual career development awards (e.g., DP5, K01, K07, K08, K22, K23, K25, K76, K99/R00), or Project Leads of program project (P01) or center grant (P50) sub-projects, or the equivalent are not eligible. Current and former PDs/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Planning Grant (R34/U34), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible, as do PD/PIs of Transition Scholar (K38) awards and individuals appointed to institutional K programs (K12, KL2).

Candidates for the K01 award must have a research or health-professional doctoral degree.

This funding opportunity may support individuals who propose to train in a new field or individuals who have had a hiatus in their research career because of illness or pressing family circumstances.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (//grants.nih.gov/grants/guide/url_redirect.php?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct, and each is from a different candidate.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. An individual may not have two or more competing NIH career development applications pending review concurrently. In addition, NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

Candidates may submit research project grant (RPG) applications concurrently with the K application. However, any concurrent RPG application may not have substantial scientific and/or budgetary overlap with the career award application. K award recipients are encouraged to obtain funding from NIH or other Federal sources either as a PD/PI on a competing research grant award or cooperative agreement, or as project leader on a competing multi-project award as described in NOT-OD-08-065 (//grants.nih.gov/grants/guide/url_redirect.php?id=51126).

Level of Effort

At the time of award, the candidate must have a full-time appointment at the applicant institution. Candidates are required to commit a minimum of nine person months of effort (i.e., 75% of full-time professional effort) to their program of career development during the mentored phase. Candidates may engage in other duties as part of the professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full time requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

After the receipt of the award, adjustments to the required level of effort may be made in certain circumstances. See NOT-OD-09-036 (https://grants.nih.gov/grants/guide/url_redirect.php?id=51125) for more details.

Mentor(s)

Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the area of the proposed research and be committed both to the career development of the candidate and to the direct supervision of the candidate's research. The mentor must document the availability of sufficient research support and facilities for high-quality research. Candidates are encouraged to identify more than one mentor, i.e., a mentoring team, if this is deemed advantageous for providing expert advice in all aspects of the research career development program. In such cases, one individual must be identified as the primary mentor who will coordinate the candidate's research. The candidate must work with the mentor(s) in preparing the application. The mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate s career stage. Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models.

Institutional Environment

The applicant institution must have a strong, well-established record of research and career development activities and faculty qualified to serve as mentors in biomedical, behavioral, or clinical research.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Career Development (K) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.php?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=51132) must be followed.

Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

The following section supplements the instructions found in the SF 424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile Expanded

All instructions in the SF424 (R&R) Application Guide must be followed.

IMPORTANT REMINDER: The personal profile associated with the eRA Commons username entered in the Credential field for the PD/PI (candidate) must include an ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the ORCID topic in our eRA Commons online help (https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D_____29).

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Career Development Award Supplemental Form

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

The PHS 398 Career Development Award Supplemental Form is comprised of the following sections:

- Candidate
- Research Plan
- Other Candidate Information
- Mentor, Co-Mentor, Consultant, Collaborators
- Environment & Institutional Commitment to the Candidate
- Other Research Plan Sections
- Appendix

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Candidate Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Candidate Information and Goals for Career Development

Candidate's Background

- Describe the candidate's commitment to a health-related research career. Describe all the candidate's professional responsibilities in the grantee institution and elsewhere and describe their relationship to the proposed activities on the career award.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.

- Provide evidence of the candidate's potential to develop into an independent investigator. Usually this is evident from publications, prior research interests and experience, and reference letters.

Career Goals and Objectives

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) that justifies the need for further career development to become an independent investigator.

Candidate's Plan for Career Development/Training Activities During Award Period

- The candidate and the mentor(s) are jointly responsible for the preparation of the career development plan. A career development timeline is often helpful.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals.
- Describe the professional responsibilities/activities including other research projects beyond the minimum required 9 person-months (75% full-time professional effort) commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Research Plan Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy

- A sound research project that is consistent with the candidate s level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.
- If the applicant is proposing to gain experience in a clinical trial, ancillary clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial.

Training in the Responsible Conduct of Research

- All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). See SF424 (R&R) Application Guide for instructions.

Mentor, Co-Mentor, Consultant, Collaborators Section

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Plans and Statements of Mentor and Co-mentor(s)

- The candidate must name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the proposed program. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
- Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the career development program and related career development activities.
- The application must include a statement from the mentor providing: 1) information on his/her research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to independent research investigator status during the project period of the award; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- Similar information must be provided by any co-mentor. If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any co-mentor is not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of face-to-face meetings.

- The primary mentor must agree to provide annual evaluations of the candidate's progress as required in the annual progress report.
- If the candidate is proposing to gain experience in a clinical trial as part of his or her research career development, the mentor or co-mentor of the mentoring team must include a statement to document leadership of the clinical trial, and appropriate expertise to guide the applicant in any proposed clinical trials research experience.

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators and/or consultants confirming their participation in the project and describing their specific roles. Collaborators and consultants do not need to provide their biographical sketches unless also listed as senior/key personnel. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.
- Advisory committee members (if applicable): Signed statements must be provided by each member of the proposed advisory committee. These statements should confirm their participation, describe their specific roles, and document the expertise they will contribute. Unless also listed as senior/key personnel, these individuals do not need to provide their biographical sketches.

Environmental and Institutional Commitment to the Candidate

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Description of Institutional Environment

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan.
- Describe the resources and facilities that will be available to the candidate.,

Institutional Commitment to the Candidate's Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide assurances that the candidate will be able to devote the required effort to activities under this award.The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist.
- Provide assurances that the candidate will have access to appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan.
- Provide assurance that appropriate time and support will be available for any proposed mentor(s) and/or other staff consistent with the career development plan.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional instructions:

o do not complete Section 4 Protocol Synopsis information or Section 5 - Other Clinical Trial-related Attachments.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

Reference Letters

Candidates must carefully follow the SF424 (R&R) Application Guide, **including the time period for when reference letters will be accepted**. Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons Submit Referee Information link (//grants.nih.gov/grants/guide/url_redirect.php?id=41146) and not through Grants.gov.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and Times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date. and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.php?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy. Any instructions provided here are in addition to the instructions in the p (//grants.nih.gov/grants/guide/url_redirect.php?id=82299)olicy.

Section V. Application Review Information

1. Criteria

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following: Reviewers should evaluate the candidate's potential for developing an independent research program that will make important contributions to the field, taking into consideration the years of research experience and the likely value of the proposed research career development as a vehicle for developing a successful, independent research program.

Overall Impact

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate s potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the reference letters address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan/Career Goals and Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

Research Plan

- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support of the proposed project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
- If proposed, will the clinical trial experience contribute to the proposed research project?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor s, consultant s, and/or collaborator s previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 9 person-months (75% of the candidate's full-time professional effort) will be devoted directly to the research and career development activities described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for the candidate's scientific and professional development of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from

research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: (1) the justification for the exemption, (2) human subjects involvement and characteristics, and (3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (https://grants.nih.gov/grants/guide/url_redirect.php?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals across the lifespan (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (https://grants.nih.gov/grants/guide/url_redirect.php?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section. (//grants.nih.gov/grants/guide/url_redirect.php?id=11150)

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not applicable

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the candidate, including any prior instruction or participation in RCR as appropriate for the candidate s career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty

involvement in the fellow s instruction; 4) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact hours are required); and 5) *Frequency of Instruction* instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as *ACCEPTABLE* or *UNACCEPTABLE*, and the summary statement will provide the consensus of the review committee. See also: NOT-OD-10-019 (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.php?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.php?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.php?id=11153).

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=11158). More specifically, for K Awards, visit the Research Career Development (K) Awardees section of the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=51164).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm (https://grants.nih.gov/grants/policy/harassment.htm).

- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the *Duncan Hunter National Defense Authorization Act of Fiscal Year 2009* (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. The Mentor's Report must include an annual evaluation statement of the candidate's progress.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applications **MUST consult the Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html)**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

GrantsInfo (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)

Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

See Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

See Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Please note that the NIH Loan Repayment Programs (LRPs) (https://www.lrp.nih.gov/) are a set of programs to attract and retain promising early-stage investigators in research careers by helping them to repay their student loans. Recipients of fellowship and career development awards are encouraged to apply for an extramural LRP award.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?05-08-20)
NIH Funding Opportunities and Notices (/grants/guide/index.html)



(/grants/oer.htm)



(https://www.hhs.gov/) Department of Health and Human Services (HHS)



(https://www.usa.gov/)

NIH... Turning Discovery Into Health®

Exhibit E to Shurtleff Declaration

FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
Regents of the University of Michigan	The Research Foundation for The State University of New York
PTE PI: Sunghee Lee	Sub PI: Elizabeth Vasquez
PTE Federal Award No: 1R01AG082080-01A1	Subaward No: SUBK00019400

Project Title: Improving Inclusivity of Alzheimer's Disease and Related Dementias Research for Asian Americans and Latinx through Nationally Representative Hybrid Sampling.

Subaward Budget Period: Start: 04/01/2024 End: 12/31/2024	Amount Funded This Action (USD): $ 5,966.00
Estimated Period of Performance: Start: 04/01/2024 End: 12/31/2028	Incrementally Estimated Total (USD): $ 26,847.00

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.

2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.

4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.

5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.

6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Administrative Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.

7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.

8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable

10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:	By an Authorized Official of the Subrecipient:
08/20/2024	Paula Kaloyeros Digitally signed by Paula Kaloyeros Date: 2024.08.19 08:48:17 -04'00'
Name: Ashley K. Tyler Date	Name: Paula Kaloyeros Date
Title: Contract Administration Senior	Title: Assistant VP, Sponsored Programs Administration

Attachment 1
Certifications and Assurances

Subaward Number: SUBK00019400

Certification Regarding Lobbying (2 CFR 200.450)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.214 and 2 CFR 180.

Audit and Access to Records
Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.332 (a)(5), 200.337, and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)
Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name
Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment
Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2
Federal Award Terms and Conditions

Subaward Number: SUBK00019400

Required Data Elements

The data elements required by Uniform Guidance are incorporated: as entered.

Awarding Agency Institute (If Applicable): NATIONAL INSTITUTE ON AGING

Federal Award Issue Date	FAIN	Assistance Listing No.
03/22/24	R01AG082080	93.866

Assistance Listing Program Title (ALPT): Aging Research

Key Personnel Per NOA: Refer to attached NOA; as applicable.

This Subaward Is:

■ Research & Development ■ Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
   https://grants.nih.gov/policy/index.htm
2. 2 CFR 200
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
   https://grants.nih.gov/policy/nihgps/index.htm
4. Applicable Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
   https://nsf.gov/awards/managing/rtc.jsp except for the following :
   a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
   b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
   c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
   d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
   e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:
Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Attached is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:
Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Grants to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):
Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

IRB Exempt and determination will be provided upon request

☒ Human Subjects Exempt

☐ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the *Principal Investigator* *as required above:*

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One) Not Applicable

This section left intentionally blank

This section left intentionally blank

Additional Terms

1. This Subaward is subject to the applicable PTE Federal Award terms and conditions. A copy of the Notice of Award ("NOA") is provided within Attachment 6.

2. Federal Identifier AG082080/Application Identifier 23-PAF04502, as submitted in response to Funding Opportunity Announcement (FOA) PAR-22-093, is incorporated herein by reference, as applicable.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: SUBK00019400

PTE Information

Entity Name: Regents of the University of Michigan

Legal Address: 3003 South State Street
Ann Arbor, Michigan 48109

Website: https://umich.edu

PTE Contacts

Central Email: subcontracts@umich.edu

Principal Investigator Name: Sunghee Lee

Email: sungheel@umich.edu Telephone Number: 734-764-8354

Administrative Contact Name: Ashley K. Tyler, Contract Administration Senior

Email: tyleras@umich.edu Telephone Number: 734-764-8256

COI Contact email (if different to above): FCOI.Reports@umich.edu

Financial Contact Name: Office of Contract Administration, Accounting Team

Email: subcontracts.accounting@umich.edu Telephone Number: 734-764-8204

Email invoices? (●) Yes ( ) No Invoice email (if different): subcontract.invoices@umich.edu

Authorized Official Name: Peter J. Gerard, Contract Administration Assistant Director

Email: subcontracts@umich.edu Telephone Number: 734-764-8204

PI Address:

SRC-ISR
426 Thompson Street
Ann Arbor, MI 48106-1248

Administrative Address:

Sponsored Programs - Office of Contract Administration
5000 Wolverine Tower
3003 South State Street
Ann Arbor, Michigan 48109-1287

Invoice Address:

Email Only: subcontract.invoices@umich.edu

Attachment 3B

Subrecipient Contacts

Subaward Number: SUBK00019400

Subrecipient Information for FFATA reporting

Entity's UEI Name: The Research Foundation for The State University of New York

EIN No.: 14-1368361

Institution Type: Nonprofit with 501c3 Status (other than Inst. of Higher Ed.)

UEI: NHH3T1Z96H29

Currently registered in SAM.gov: (•) Yes ( ) No

Exempt from reporting executive compensation: (•) Yes ( ) No *(if no, complete 3Bpg2)*

Parent UEI:

This section for U.S. Entities:

Zip Code Look-up

Congressional District: NY-020

Zip Code+4: 12222-0100

Place of Performance Address

1400 Washington Ave, Albany, NY

Subrecipient Contacts

Central Email: preaward@albany.edu

Website: https://www.albany.edu/spa/indexmain.php

Principal Investigator Name: Elizabeth Vásquez

Email: evasquez2@albany.edu Telephone Number: 518-408-2362

Administrative Contact Name: Todd Remkus

Email: preaward@albany.edu Telephone Number: 518-442-3196

Financial Contact Name: Jerold Gauriloff

Email: amsfr@albany.edu Telephone Number: 518-442-3196

Invoice Email: amsfr@albany.edu

Authorized Official Name: Paula Kaloyeros

Email: preaward@albany.edu Telephone Number: 518-442-3196

Legal Address:

1400 Washington Ave., MSC 100A
Albany, NY 12222-0100

Administrative Address:

1400 Washington Ave., MSC 100A
Albany, NY 12222-0100

Payment Address:

The Research Foundation for the SUNY
Treasurer's Office
PO Box 9
Albany, NY 12201-0009

Attachment 3B-2

Highest Compensated Officers

Subaward Number: SUBK00019400

Subrecipient:

Institution Name: Michigan State University

PI Name: Elizabeth Vásquez

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and $25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: SUBK00019400

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of of the end of the month.

☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact.

☐ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Administrative Contact. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.

☐ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 60 days of the end of the Project Period or after termination of this award, whichever comes first.

■ Technical/progress reports on the project as may be required by PTE's Principal Investigator in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:
Carryover is automatic

Other Reports:

■ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Financial Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Financial Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: Yes

☐ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional Technical and Reporting Requirements:

Closeout documents: The closeout documents provided within Attachment 6 must to be completed and returned along with the Final Invoice.

Invoicing Instructions: Invoices shall be e-mailed to subcontract.invoices@umich.edu for processing. In addition to the invoicing terms and conditions identified on the face page of the Subaward each invoice must include the following:

a. PO Number: 3008154128
b. A unique invoice number: Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of Michigan contracts or orders held by an organization.
c. Invoice period: The period for which the expenditures apply
d. Remittance address
e. Per face page, each invoice must include a certification, signed by an official who is authorized to legally bind the non-Federal entity, which reads as follows: "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812)."

Sufficient detail must be provided to allow for PTE review of invoices. Additional detail or supporting documentation, requested on an as-needed basis, will be made available upon request.

Subaward Number: SUBK00019400

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Statement of Work

( ) Below (•) Attached, 1 pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

This section left intentionally blank.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied	56.50 %	**Cost Sharing**	No
Rate Type:	Modified Total Direct Costs	If Yes, include Amount: $	

Budget Details

( ) Below (•) Attached, 3 pages

Subrecipient is responsible for making sure that costs incurred/charged are allowable in accordance with the terms and conditions of the Federal award.

Budget Totals

Direct Costs	$ 3,812.00
Indirect Costs	$ 2,154.00
Total Costs	$ 5,966.00

All amounts are in United States Dollars

University at Albany – SUNY

9/1/23-8/31/28

STATEMENT OF WORK

Project Summary:

Reported racial and ethnic disparities associated with ADRD in the extant literature are mainly for Blacks and Latinx. These two groups experience a higher rate of ADRD prevalence as well as missed diagnosis than Whites. At the same time, studies based on the members of a health plan in Northern California that illustrated lower ADRD prevalence among Asian Americans than Whites and prevalence heterogeneity within Asian Americans offer a glimpse into **dynamics of ADRD across racial and ethnic groups which need to extend beyond minimum standard racial/ethnic categories** (e.g., Chinese rather than Asian). Unfortunately, **population-level ADRD research data are absent beyond White, Blacks and Latinxs** due to lacking statistical power. For granular subgroups, data collection is exorbitantly expensive. Low research participation by racial and ethnic diverse individuals presents challenges even with unlimited resources. This study aims to introduce a hybrid adaptive Web-based respondent driven sampling under the multiple frame estimation framework as a practical sampling and data collection method in order to address the lack of racial and/or ethnic minority data among older adults. The Hybrid Adaptive Web-based respondent driven sampling (H-WRDS) recruits participants through peer referrals within existing social networks, administers data collection on the Web and adapts its design aspects based on the incoming data in order to generate data mirroring the theoretical underpinning of RDS. Strong social ties with their own group and high Web penetration rates among racial and ethnic minorities older adults in the U.S. make H-WRDS a strong candidate as a practical data collection method; however, its practice as well as the data quality remain to be verified. This project is well suited to deliver **a fuller picture of ADRD-related disparities, data collection methods overcoming such barriers are critically needed** particularly in the era of COVID-19 that has brought racial and ethnic health disparities to the surface. This study aims to address the lack of inclusive ADRD research data by **establishing a national panel through hybrid web respondent driven sampling (H-WRDS)**, to examine **the role of culturally sensitive social engagement as a mediator.**

Project tasks and deliverables:

- Assist the PI (Dr. Lee) and her team with the implementation and execution of the formative project
- Lead Spanish language adaptations on survey instruments and respondent communication materials
- Supervise RAs assigned to the Spanish portion of the survey who will handle respondent inquiries and conduct phone survey interviews.
- Lead Latinx in-depth interviews (n=10) and Co-lead questionnaire development
- Review data analysis and propose suggestions to enhance the scope of the data analysis
- Assist the team with the interpretation of the data
- Assist with the drafting of project reports and scientific manuscripts and presentations
- Participate in survey protocol development and Aim 2 analysis (social network as a mediator of racial/ethnic disparities of ADRD risks).
- Participate in teleconference and video-enabled meetings, when needed

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 12/31/2022

UEI: NHH3T1Z96H29 **Enter name of Organization:** The Research Foundation for SUNY, University at Albany

Budget Type: ☐ Project ☒ Subaward/Consortium **Budget Period: 1** **Start Date:** 04/01/2024 **End Date:** 12/31/2024

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
Dr.	Elizabeth		Vasquez					0.30	3,344.00	468.00	3,812.

Project Role: Co-Investigator

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person 3,812.

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) 3,812.

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C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees / **Total Participant/Trainee Support Costs**	

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F. Other Direct Costs

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	3,812.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
MTDC	56.50	3,812.00	2,154.00

Total Indirect Costs	2,154.00

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Ryan McCarthy, 212-264-2069

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	5,966.00

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	5,966.00

L. Budget Justification

(Only attach one file.) 3 Budget Justification UAlbany Vasque: Add Attachment | Delete Attachment | View Attachment

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Subaward Number:
SUBK00019400

Attachment 6

Notice of Award (NOA) and any additional documents

◉ The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.

○ Not incorporating the NOA or any additional documentation to this Subaward.

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG082080
Federal Award Date
03/22/2024

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF MICHIGAN
1109 GEDDES AVE, SUITE 3300
ANN ARBOR, MI 48109

2. Congressional District of Recipient
06

3. Payment System Identifier (ID)
1386006309A1

4. Employer Identification Number (EIN)
386006309

5. Data Universal Numbering System (DUNS)
073133571

6. Recipient's Unique Entity Identifier
GNJ7BBP73WE9

7. Project Director or Principal Investigator
Sung-Hee Lee, PHD
Research Associate Professor
sungheel@umich.edu
734-764-8354

8. Authorized Official
Mr. Reynaldo Martell
martellr@umich.edu
734-647-9099

Federal Agency Information

9. Awarding Agency Contact Information
Maurice Koo
Extramural Support Assistant
NATIONAL INSTITUTE ON AGING
koom@mail.nih.gov
3014351135

10. Program Official Contact Information
John Phillips
Health Scientist Administrator
NATIONAL INSTITUTE ON AGING
john.phillips@nih.gov
301 5551212

Federal Award Information

11. Award Number
1R01AG082080-01A1

12. Unique Federal Award Identification Number (FAIN)
R01AG082080

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Improving Inclusivity of Alzheimer's Disease and Related Dementias Research for Asian Americans and Latinx through Nationally Representative Hybrid Sampling.

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2024 **– End Date** 12/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$979,196
20 a. Direct Cost Amount	$627,690
20 b. Indirect Cost Amount	$351,506
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$979,196
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$979,196
26. Project Period Start Date 04/01/2024 **– End Date** 12/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$979,196

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jessica Perez

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R01AG082080-01A1

Principal Investigator(s):
Sung-Hee Lee, PHD

Award e-mailed to: swhite-gov@umich.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $979,196 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the University of Michigan in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG082080. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jessica Perez
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$385,105

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Fringe Benefits	$82,216
Personnel Costs (Subtotal)	$467,321
Consultant Services	$6,000
Materials & Supplies	$36,003
Other	$111,400
Subawards/Consortium/Contractual Costs	$5,966
ADP/Computer Services	$1,000
Federal Direct Costs	$627,690
Federal F&A Costs	$351,506
Approved Budget	$979,196
Total Amount of Federal Funds Authorized (Federal Share)	$979,196
TOTAL FEDERAL AWARD AMOUNT	$979,196
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$979,196

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$979,196	$979,196
2	$1,191,854	$1,191,854
3	$820,279	$820,279
4	$1,197,455	$1,197,455
5	$727,144	$727,144

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1386006309A1
Document Number:	RAG082080A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027	2028
AG	8033157	$979,196	$1,191,854	$820,279	$1,197,455	$727,144

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 2CECNJP / **OC**: 41021 / **Released**: Perez, Jessica 03/13/2024
Award Processed: 03/25/2024 04:55:38 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG082080-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AG082080-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AG082080. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 1R01AG082080-01A1

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with The Research Foundation for SUNY, University at Albany in the amount of $5,966 ($3,812 direct costs + $2,154 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 01/01. The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS

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plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
DMS Costs	$0	$0	$0	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG082080-01A1

INSTITUTION: The Regents of the University of Michigan

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$385,105	$419,428	$362,778	$422,088	$350,540
Fringe Benefits	$82,216	$83,652	$75,963	$84,395	$75,965
Personnel Costs (Subtotal)	$467,321	$503,080	$438,741	$506,483	$426,505
Consultant Services	$6,000	$6,000	$6,000	$6,000	$6,000
Materials & Supplies	$36,003	$9,982	$16,341	$14,592	$2,890
Travel		$8,500	$8,500	$8,500	$8,500
Other	$111,400	$225,700	$40,300	$215,700	$1,600
Subawards/Consortium/ Contractual Costs	$5,966	$5,966	$5,966	$2,983	$5,966
Publication Costs			$5,000	$3,000	$3,000
ADP/Computer Services	$1,000				$902
Tuition Remission		$7,458	$7,756	$16,133	$16,778
TOTAL FEDERAL DC	$627,690	$766,686	$528,604	$773,391	$472,141
TOTAL FEDERAL F&A	$351,506	$425,168	$291,675	$424,064	$255,003
TOTAL COST	$979,196	$1,191,854	$820,279	$1,197,455	$727,144

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	56%	56%	56%	56%	56%
F&A Cost Base 1	$627,690	$759,228	$520,848	$757,258	$455,363
F&A Costs 1	$351,506	$425,168	$291,675	$424,064	$255,003

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OMB No. 0925-0001 and 0925-0002 *(Rev. 07/2022 Approved Through 01/31/2026)*

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001 and 0925-0002). Do not return the completed form to this address.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:

The proposed study will provide the following seven scientific datasets.

1. Nationally representative cross-sectional data on a target sample of 5,000 middle-age and older adults (ages 40 years old or older) at the baseline on topics related to cognitive health and social networks.
2. The baseline recruitment tracking data. With the use of respondent driven sampling where participants recruit their own peers through recruitment coupons, who recruited who can be ascertained.
3. Nationally representative cross-sectional data on a target sample of 5,000 middle-age and older adults (ages 40 years old or older) at Wave 2 on topics related to cognitive health and social networks.
4. Wave 2 recruitment tracking data.
5. Longitudinal data on a target sample of 2,500 adults ages 40 years old or older by following back the baseline participants at Wave 2 and assuming a 50% follow-back rate on topics related to cognitive health and social networks.
6. Interviewer-administered virtual interview data on 300 middle-age and older adults subsampled from the baseline respondents focusing on verifying and validating self-reported cognitive health in the baseline survey.
7. Experimental survey data on emerging topics related to cognitive health with 2500 subsampled from the baseline respondents.

It should be noted approximately 70% of the sample across all datasets will be seven granular minority groups our study targets: Afro-Latinx, nonAfro-Latinx, Chinese, Asian Indian, Filipino, Korean and Vietnamese.

The raw data will be recoded to characterize missing values, for top coding or collapsing variable categories, or other activities as needed.

B. Scientific data that will be preserved and shared, and the rationale for doing so:

The raw interview data and recruitment tracking data will be stored within a secure computing environment. All direct respondent identifiers (e.g., names, addresses) will be removed and maintained separately in a secure file for future contact purposes.

All other scientific data listed in Element 1.A will be both preserved and shared. Respondent identifiers will not be shared.

C. Metadata, other relevant data, and associated documentation:

Documentation to be made publicly available to the research community will include a text version of the questionnaires with programming specifications (e.g., skip patterns), detailed user guides, codebooks with descriptive statistics for each variable, and study-level metadata following the Data Documentation Initiative (DDI) specification. Each variable in the codebooks will include a brief description of the item along with the question number from the questionnaires, variable name, variable label, value labels, and standard codes for missing values—including codes for non-applicable, "don't know," and refusal. These documents will be provided in portable document format (PDF).

Element 2: Related Tools, Software and/or Code:

Scientific data will be processed and analyzed in R and shared in many widely accessible formats, including ASCII, CSV, tab-delimited text (including Excel), SAS, SPSS and Stata.

This project will develop a web-based sample management system (SMS) that operates on a virtual server running MS-IIS as described in Research Strategy. This technical system is a key for automatizing the study operations, while maintaining PII separately. The system shell, its code and documentation (in portable document format) will be disseminated to the public.

Element 3: Standards:

To facilitate data use, the study will use standard DDI-based processing and documentation protocols adopted by the Inter-university Consortium for Political and Social Research (ICPSR) for data formats and dictionaries as well as for variable names, descriptions, and labels.

Variable descriptions include a brief explanation of the questionnaire item content or of the constructed measure. Value labels tie individual numeric response codes to descriptive responses from the questionnaire.

Survey interview questions will be primarily based on the Health and Retirement Study and other established studies. Demographic, economic, and relationship questions will be based on Office of Management and Budget (OMB) standards or the International Standard Classification of Education (ISCED) standards.

In addition to DDI, our approach for data management and sharing plan follows the FAIR guiding principles which, we expect, will improve Findability, Accessibility, Interoperability, and Reusability of the proposed study protocols as well as data. The first step to our resource sharing plan is to create a persistent unique study identifier that will be attached to all documentation, publication, and data resulting from this data. This identifier system will allow our products to be easily identifiable.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:

Public use and restricted access study data and associated documentation will be made available to the research community free of charge through the National Archive of Computerized Data on Aging (NACDA) data repository hosted at ICPSR.

B. How scientific data will be findable and identifiable:

Datasets in ICPSR-NACDA will be findable and identifiable through a study digital object identifier (DOI) minted by ICPSR.

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C. When and how long the scientific data will be made available:

We plan to deposit the study data approximately 8-12 months following the end of each fieldwork, respectively, and within the award period. Study data deposited in ICPSR-NACDA will be available to the research community in perpetuity.

Datasets underlying methodological publications will be shared at or prior to initial publication date.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

No additional limitations other than the controls and privacy protections described below.

B. Whether access to scientific data will be controlled:

Public Use Data: All deidentified study data that are not designated as restricted use will be made available as public use data to the research community through ICPSR-NACDA. Users of the public use data must register with ICPSR and agree to the Terms of Use, which are designed to protect study participants by limiting data use to scientific research and aggregate statistical reporting, prohibiting attempts to identify study participants, and requiring immediate reporting of any disclosure of study participant identity. Data users also agree not to share or redistribute any data downloads.

Restricted Access Data: Data that are determined to be potentially identifying through indirect or deductive disclosure are provided under restricted data contract to users who demonstrate a valid research need and meet conditions of use. These restricted data will include separate files with recruitment tracking information (i.e., who recruited who) and geospatial indicators below the level of state, such as ZIP code. Access to restricted study data is available through ICPSR-NACDA includes an approved user agreement, a virtual data enclave system, or online access with applying disclosure protection. We will work with ICPSR-NACDA for the most suitable option.

C. Protections for privacy, rights, and confidentiality of human research participants:

Once the data collection concludes, all direct respondent identifiers (e.g., names, addresses) will be removed and maintained in a separate control file for future contact purposes. Participants' identifying information is only accessed by approved staff as part of the project duties within a secure computing environment. Deidentification will be completed by the end of data processing, prior to the finalization of the public use and restricted data files.

Our informed consent form will ask study participants to consent to data collection and sharing with the wider research community. The privacy, rights, and confidentiality of human subject participants in this study will be protected through the suppression of all direct respondent identifiers, the careful classification of any potentially identifying data as restricted access, the high security standards through which the ICPSR-NACDA provides access to restricted data for approved researchers, and the project's Certificate of Confidentiality.

Element 6: Oversight of Data Management and Sharing:

The Principal Investigator of the proposed study will be responsible for monitoring of and compliance with this Data Management and Sharing Plan. The plan will be implemented and managed by professional staff (postdoc) working under the direction of the PI.

RESOURCE SHARING PLAN

There are two distinctive deliverables from the proposed study: 1) datasets from a national survey of older adults (ages ≥ 40 years old) along with study materials (e.g., questionnaires in multiple languages) and 2) software for the mixed-mode hybrid sampling (HybS) sample management system (SMS).

These deliverables will be prepared as follows:
1) The datasets along with data collection instruments (e.g., questionnaires) will be deposited at the Interuniversity Consortium for Political and Social Research (ICPSR). Our budget includes ICPSR curation service fees for datasets, including recruitment information, which requires data confidentiality reviews. With the ICPSR curation service, our data sets will be available to the public; and
2) The HybS SMS will be developed as a Web-based system along with a manual and source code.

To streamline the dissemination of these deliverables, we will develop a website designated to our study and make these deliverables, or an access to them, available. We will also include a test-version of the HybS SMS on the website.

For a broader dissemination of the deliverables, we will work with professional organizations (e.g., the Gerontological Society of America, the American Public Health Association, the American Statistical Association, the American Association for Public Opinion Research) to participate in their webinars and other educational venues.

Drs. Lee, Hu, Ajrouch, Freidman, Elliott, Couper, Langa, Kim and Paulson's appointments at the University of Michigan's ISR and Michigan Medicine are particularly advantageous for this. In particular, Dr. Lee is an MPI of the NIA-funded Network for Innovative Methods in Longitudinal Aging Studies (NIMLAS) recently launched to promote methodological advance in aging studies. Dr. Langa is Associate Director of the Health and Retirement Study (HRS) and Director of the Center to Accelerate Population Research in Alzheimer's (CAPRA); Drs. Lee and Couper are participating investigators of HRS; Dr. Friedman is Associate Director of the Panel Study of Income Dynamics (PSID), a PI of the Longitudinal Studies of Aging Network (LSOA) and a Co-I of NIMLAS; Dr. Hu is one of the investigators of the National Health and Aging Trends Study (NHATS); Drs. Lee, Friedman, Ajrouch, Hu, and Langa are with the Michigan Center on the Demography of Aging (MiCDA); Dr. Ajrouch is Director of the Michigan Center for Contextual Factors in Alzheimer's Disease (MCCFAD); and Dr. Paulson is Director of the Michigan Alzheimer's Disease Research Center (ADRC).

A synergy may be expected across the proposed study, NIMLAS, HRS, NHATS, PSID, LOSA, CAPRA, MiCDA, MCCFAD and Michigan ADRC for the dissemination of the datasets and findings from the proposed study. Drs. Lee, Couper, Elliott and Kim teach through the ISR-Summer Institute, which already offers an education program on broader sampling and survey design issues. If HybS is proven to be effective, we plan to offer a course on this topic. Additionally, we will work closely with the ADRD and health disparity research communities to disseminate our approaches. As Drs. Ajrouch, Langa, Paulson, Vásquez and Lee are deeply involved in such research communities, our research team is well positioned to deliver our findings to the pertinent audience.

Form Approved Through 10/31/2018
OMB No. 0925-0002

Department of Health and Human Services

Final Invention Statement and Certification

(For Grant or Award)

DHHS Grant or Award No.

A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

_____ through _____ .

original effective date *date of termination*

B. Inventions (Note: If no inventions have been made under the grant or award, insert the word *"NONE"* under

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS
(Use continuation sheet if necessary)		

C. Signature — This block ***must*** be signed by an official authorized to sign on behalf of the institution.

Title		Name and Mailing Address of Institution
Typed Name		
Signature	Date	

Exhibit F to Shurtleff Declaration



March 12, 2025

Amy Lagowski
Research Foundation for the State University of New York
Amy.Lagowski@buffalo.edu

Dear Amy Lagowski:

Funding for Project Number 1P50MD019473-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 19, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit G to Shurtleff Declaration

Wshen7@buffalo.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:31 PM
To: Wei Shen <wshen7@buffalo.edu>
Subject: Grant Termination Notification



3/21/2025

Wei Shen
State University Of New York At Buffalo
wshen7@buffalo.edu

Dear Wei Shen:

Effective with the date of this letter, funding for Project Number 5K01MH130270-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.***[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents [12]

supporting your claim.

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Exhibit H to Shurtleff Declaration



3/21/2025

Mical, Alison
State University Of New York At Buffalo
alodojew@buffalo.edu

Dear Mical, Alison:

Effective with the date of this letter, funding for Project Number 5R01AA028810-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Exhibit I to Shurtleff Declaration

Deputy Operations Manager
Sponsored Programs Administration
University at Albany, MSC 100A
1400 Washington Ave, Albany, NY 12222
Ph: (518) 442-3196
Web: http://www.albany.edu/spa



From: Romand, Doris A <dromand@albany.edu>
Sent: Friday, March 21, 2025 3:25 PM
To: Kaloyeros, Paula M <pkaloyeros@albany.edu>
Cc: Marshall, Nicole <nmarshall@albany.edu>; Gauriloff, Jerold E <jgauriloff@albany.edu>; Remkus, Todd A <tremkus@albany.edu>
Subject: FW: STOP ALL WORK - Permanent - Fwd: Grant Termination Notification [AWD026538]

This is the University of Michigan subaward for Elizabeth Vasquez.

Best Regards,
Doris

From: Vasquez, Elizabeth <evasquez2@albany.edu>
Sent: Friday, March 21, 2025 3:13 PM
To: Romand, Doris A <dromand@albany.edu>
Subject: FW: STOP ALL WORK - Permanent - Fwd: Grant Termination Notification [AWD026538]

Hola Doris! Not sure if you are the one to get this..

From: Sunghee Lee <sungheel@umich.edu>
Sent: Friday, March 21, 2025 2:57 PM
To: SMART Managers <smart-managers@umich.edu>; SMART Investigators <smart-investigators@umich.edu>; SMART RAs <smart-ras@umich.edu>
Cc: April Miller <millean@umich.edu>; Nancy Oeffner <oeffner@umich.edu>; Kara Cristian <kcri@umich.edu>
Subject: Fwd: STOP ALL WORK - Permanent - Fwd: Grant Termination Notification [AWD026538]

Hi Team,

This is really hard to relay. We have received a Stop Work order on the SMART as you see in the email below.

We will be exploring all options regarding this order. Please stay tuned for updates. For now, we will need to stop all SMART related activities. This includes cancelling all interviews that have been scheduled.

Sunghee

---------- Forwarded message ---------
From: **Reynaldo Martell** <martellr@umich.edu>
Date: Fri, Mar 21, 2025 at 2:29 PM
Subject: STOP ALL WORK - Permanent - Fwd: Grant Termination Notification [AWD026538]
To: Sunghee Lee <sungheel@umich.edu>, Kara Cristian <kcri@umich.edu>, April Miller <millean@umich.edu>

Good afternoon,

Please see the email below regarding AWD026538. This notice terminates this project as of 03/21/2025.

Rey

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <michelle.bulls@nih.gov>
Date: Fri, Mar 21, 2025 at 12:29 PM
Subject: Grant Termination Notification
To: martellr@umich.edu <martellr@umich.edu>

3/21/2025
Reynaldo Martell
University Of Michigan At Ann Arbor
martellr@umich.edu

Dear Reynaldo Martell:
Effective with the date of this letter, funding for Project Number 5R01AG082080-02 is hereby

terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 1/1/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.***[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

--
Reynaldo Martell
Senior Award Management Officer
734-647-9099 | martellr@umich.edu
University of Michigan | Office of Research and Sponsored Projects (ORSP)
3003 S. State Street | 1036 Wolverine Tower | Ann Arbor, MI 48109-1274

For U-M Personnel: Help us deliver quality service by providing a PAF, UFA, or P/G number along with the PI's name whenever you contact ORSP. Up-to-date project status information is available in eRPM.

Exhibit J to Shurtleff Declaration

FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 01
PTE/Prime Award No.: 1R01HL169503-01A1
Subaward No: F2538-01

Pass-Through Entity (PTE)		Subrecipient
New York University	Entity Name	The Research Foundation for the State University of New York
osp.agency@nyu.edu	Contact Email	grants-office@downstate.edu
Stephanie Cook	Principal Investigator	Jason Lazer

Project Title: Geographically-Explicit Ecological Momentary Assessment Protocol to Assess the Linkages Between Intersectional Discrimination and CVD Risk Among Sexual and Gender Minorities

Cumulative Budget Period(s) (Agreement Start Date)	(End Date of Latest Budget Period)	Amount Funded This Action	Total Amount of Funds Obligated to Date
Start Date: 04/01/2024	End Date: 03/21/2025	$ 0.00	$ 28,535.00

Subrecipient Cost Share ☐ | Subject to FFATA ■ | Subrecipient UEI (Unique Entity Identifier - May leave blank if unchanged from prior Agreement): NJ14V2NZYM68

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Subaward Agreement as follows:

In accordance with the attached 'Grant Termination Notification' received by New York University (NYU) from the National Institutes of Health (NIH) dated March 21, 2025, this Agreement is hereby terminated effective March 21, 2025.

Effective immediately upon receipt of this termination notice from NYU the Subrecipient must stop all work on the Project and must not incur any new costs after March 21, 2025, Subrecipient must cancel as many outstanding obligations as possible.

Subrecipient must send an invoice and financial report, detailing all expenses and costs incurred since Subrecipient's most recent previous invoice through and including March 21, 2025, to NYU as soon as possible but no later than within 30 days of the effective date of this termination

Carryover is **Not Applicable**

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
_____	Date	_____	Date
Name		Name	
Title		Title	

NYU

Jiaan Sa <saj01@nyu.edu>

A25-0556 - CookS - Fwd: Grant Termination Notification

1 message

osp.agency@nyu.edu <nyu194@nyu.edu> Fri, Mar 21, 2025 at 1:21 PM
Reply-To: osp.agency@nyu.edu
To: Jason St Germain <stgerj01@nyu.edu>
Cc: Sponsored Programs Administration <cdv.spa@nyu.edu>, Jasmine Rodriguez <jyr1@nyu.edu>, Jiaan Sa <saj01@nyu.edu>

--
Angela Mai
Office of Sponsored Programs
New York University
665 Broadway, Suite 801
New York, NY 10012
212.998.2121(t)

Reply to: osp.agency@nyu.edu
Homepage: nyu.edu/osp
Team Assignments: Grants & Contracts

Please consider the environment before printing this email.

---------- Forwarded message ---------
From: **'Bulls, Michelle G. (NIH/OD) [E]' via OSP.Agency** <osp.agency-group@nyu.edu>
Date: Fri, Mar 21, 2025 at 1:19 PM
Subject: Grant Termination Notification
To: osp.agency@nyu.edu <osp.agency@nyu.edu>

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

St Germain, Jason

New York University

osp.agency@nyu.edu

Dear St Germain, Jason:

Effective with the date of this letter, funding for Project Number 1R01HL169503-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (“NIH”) Grants Policy Statement,[1] and 2

C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 4/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Anthony Agresti, Chief Grants Management Officer, NHLBI

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Notice of Award
FAIN# R01HL169503
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
NEW YORK UNIVERSITY
70 WASHINGTON SQ S
NEW YORK, NY 10012

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1135562308A1

4. Employer Identification Number (EIN)
135562308

5. Data Universal Numbering System (DUNS)
041968306

6. Recipient's Unique Entity Identifier
NX9PXMKW5KW8

7. Project Director or Principal Investigator
Stephanie Hazel Cook, DRPH
Assistant Professor
sc5810@nyu.edu
212-998-5525

9. Authori8ed z fficial
Jason St Germain
osp.agency@nyu.edu
212-998-2121

Federal Agency Information

O. Awarding Agency Contact Information
James Hennigan
Grants Management Specialist
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
james.hennigan@nih.gov
(301) 480-7071

10. Program z fficial Contact Information
ALISON GWENDOLYN MARY Brown

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
alison.brown@nih.gov
301-435-0583

Federal Award Information

11. Award Number
1R01HL169503-01A1

12. Unique Federal Award Identification Number (FAIN)
R01HL169503

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Geographically-Explicit Ecological Momentary Assessment Protocol to Assess the Linkages Between Intersectional Discrimination and CVD Risk Among Sexual and Gender Minorities

15. Assistance Listing Number
93.837

16. Assistance Listing Program Title
Cardiovascular Diseases Research

17. Award Action Type
New Competing (REVISED)

19. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
1O. Budget Period Start Date 04/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds z bligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$636,567
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$636,567
26. Project Period Start Date 04/01/2024 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$636,567

29. Authori8ed Treatment of Program Income
Additional Costs

2O. Grants Management z fficer - Signature
Anthony Agresti

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

SECTIz N I – AWARD DATA – 1R01HL16O503-01A1 RE: ISED

Principal Investigator(s)Y
Stephanie Hazel Cook, DRPH

Award e-mailed toYosp.agency@nyu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to NEW YORK UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number R01HL169503. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Anthony Agresti
Grants Management Officer
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$229,874

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Fringe Benefits	$71,260
Personnel Costs (Subtotal)	$301,134
Consultant Services	$15,000
Materials & Supplies	$8,000
Travel	$5,000
z ther	$21,330
Subawards\Consortium\Contractual Costs	$57,070
Federal Direct Costs	$407,534
Federal F&A Costs	$229,033
Approved Budget	$636,567
Total Amount of Federal Funds Authori8ed (Federal Share)	$636,567
Tz TAL FEDERAL AWARD AMz UNT	$636,567
AMz UNT z F THIS ACTIz N (FEDERAL SHARE)	$0

SUMMAR/ Tz TALS Fz R ALL / EARS (for this Document Number)		
/ R	**THIS AWARD**	**CUMULATI: E Tz TALS**
1	$636,567	$636,567

Fiscal InformationY

Payment System IdentifierY	1135562308A1
Document NumberY	RHL169503A
PMS Account TypeY	P (Subaccount)
Fiscal / earY	2024

IC	CAN	2024
HL	8475146	$636,567

NIH Administrative DataY
PCC: HHCBMN / **z C**: 41021 / **Released**: 03/24/2025
Award ProcessedY03/25/2025 12:11:34 AM

SECTIz N II – PA/ MENTVHz TLINE INFz RMATIz N – 1R01HL160503-01A1 RE: ISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTIz N III – STANDARD TERMS AND Cz NDITIz NS – 1R01HL160503-01A1 RE: ISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D)Y All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to

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report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HL169503. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program IncomeY
Additional Costs

SECTIz N I: – HL SPECIFIC AWARD Cz NDITIz NS – 1R01HL160503-01A1 RE: ISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATIz N
It is the policy of NIH not to prioritize Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Therefore, this project is terminated. NEW YORK UNIVERSITY may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed

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and recovered. Please be advised that your organization, as part of the orderly Closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant. NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

REVISION #2 - RESTORATION OF FUNDS

This revised award increases the Total Costs authorized consistent with the NIH fiscal policy for FY2024. The NHLBI Operating Guidelines can be found at: http://www.nhlbi.nih.gov/research/funding/general/current-operating-guidelines

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REVISION #1 - ADMINISTRATIVE UPDATE

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This award has been revised to process an NHLBI administrative revision regarding human subjects coding on this award. No action is required from New York University.

All previous terms and conditions remain in effect

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CONSORTIUM/CONTRACTUAL
This award includes funds awarded for consortium activity with Downstate College of Medicine (SUNY). The recipient, as the direct and primary recipient of NIH grant funds, is accountable to NIH for the performance project, the appropriate expenditures of grant funds by all parties, and all other obligations of the recipient, as specified in the NIH Grants Policy Statement. In general, the requirements that apply to the recipient, including the intellectual property requirements also apply to consortium participant(s).

KEY PERSONNEL
In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires written prior approval of the National Institutes of Health awarding component.

Mari Armstrong-Hough

GRADUATE STUDENT COMPENSATION
In accordance with the Guide Notice: NOT-OD-02-017, published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide notice describing the Fiscal Year 2023 level of compensation allowed for a graduate student can be found at: NOT-OD-23-076.

OTHER SUPPORT REMINDER INFORMATION
This award is contingent upon the following: No individual who receives salary support from this project may receive compensation for more than 12 calendar months (i.e., 100%) total effort from all of their sources of support.

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SALARY CAP
None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. This award and/or future years may have been adjusted accordingly. Current salary cap levels can be found at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

PRIOR APPROVAL REQUEST
It is recommended that applicable prior approval requests be submitted via the eRA Commons Prior Approval Module (link: prior_approval (nih.gov)). Please refer to Part II Chapter 8 of the NIH Grants Policy Statement for the activities and/or expenditures that require NIH approval at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

NON-COMPETING RENEWAL (SNAP)
The NIH requires the use of the Research Performance Progress Report (RPPR) for all Type 5 progress reports. The RPPR and other documents applicable to this SNAP grant are due the 15th of the month preceding the month in which the budget period ends (e.g., if the budget period ends 11/30, the due date is 10/15). Please see http://grants.nih.gov/grants/rppr/index.htm for additional information on the RPPR.

FOREIGN TRAVEL
Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMAR/
AWARD NUMBERY1R01HL169503-01A1 REVISED

INSTITUTIz NYNEW YORK UNIVERSITY

Budget	Year 1
Salaries and Wages	$229,874
Fringe Benefits	$71,260
Personnel Costs (Subtotal)	$301,134
Consultant Services	$15,000
Materials & Supplies	$8,000
Travel	$5,000
Other	$21,330
Subawards/Consortium/Contractual Costs	$57,070
TOTAL FEDERAL DC	$407,534
TOTAL FEDERAL F&A	$229,033
TOTAL COST	$636,567

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Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	61%
F&A Cost Base 1	$375,464
F&A Costs 1	$229,033

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EXHIBIT 25

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF AMY HEQUEMBOURG

I, Amy Hequembourg, PhD, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am an associate professor of the State University of New York University at Buffalo in the School of Nursing.

2. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the University at Buffalo staff including my Co-Principal Investigator Jennifer Livingston, PhD, or from documents that have been provided to and reviewed by me.

3. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

4. I am an associate professor at the University at Buffalo School of Nursing, dedicated to investigating health disparities among sexual and gender minoritized (SGM) populations. My research has identified risks associated with sexual victimization among sexual

minority women, offering insights into their unique post-assault disclosure and coping experiences. I have also contributed to understanding the distinct health challenges faced by bisexual women. Collaborating with interdisciplinary teams, my work explores the link between alcohol use and violence within SGM communities. My current funded research examines mechanisms linking peer victimization and alcohol use among lesbian, gay, bisexual queer and individuals who identify as something other than exclusively heterosexual (LGBQ+) adolescents.

5. The University at Buffalo is a scholarly community dedicated to bringing the benefits of our research, scholarship, creative activities and educational excellence to local and global communities in ways that impact and positively change the world.

The University views the three traditional pillars of the public higher education mission—research, education and service—as interdependent endeavors that continually enrich and inform each other. Groundbreaking research, transformative educational experiences and deeply engaged service to our communities define the University at Buffalo's mission as a premier, research-intensive public university.

6. University at Buffalo, a flagship of the State University of New York, has three campuses, over 32,000 students, almost 12,000 employees, and performs over $544,000,000.00 in vital research annually.

Reliance on NIH Funding

7. In fiscal year 2024, University at Buffalo received funding through the National Institutes of Health ("NIH") to support 224 projects, totaling $60,654,347.

8. University at Buffalo receives NIH grants across a variety of institutes encompassed within the NIH, including the National Institute on Minority Health and Health

Disparities, the National Institute of Mental Health, and the National Institute for Alcohol Abuse & Alcoholism.

9. Through those NIH grants, University at Buffalo funds 1,003 researchers.

10. The work done by University at Buffalo on NIH funded projects provides education and training in Biomedical Engineering, Biochemistry, Chemistry, Dentistry, Family Medicine; Internal Medicine; Microbiology and Immunology, Neurology, Nursing, Ophthalmology, Pathology, Pediatrics, Pharmacology, Psychology, Public Health and Health Professions, Radiology, and other programs.

11. University at Buffalo provides considerable employment benefits in the Science, Technology, Engineering and Mathematics workforce to the New York State economy.

Terminations of NIH Grants

12. Since March 12, 2025, University at Buffalo has had three NIH grants terminated, not including terminated grants for which the University was a sub-awardee.

13. The terminations received as of March 28, 2025 are attached hereto as Exhibits A–C.

14. These terminations will result in the loss of at least $4,481,711 in research funding to University at Buffalo.

15. The termination notices for these grants have provided very little to explain the termination, instead noting that the research is no longer consistent with newly conceived agency priorities. Specifically, the termination notices state that: "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do

not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."

16. In my 19 years working in NIH funded research at University at Buffalo, I have not seen this language previously used to cancel grants.

17. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, University at Buffalo had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was University at Buffalo provided with any updated "agency priorities" with which its research must align.

18. I am the Co-Principal Investigator (with Jennifer Livingston, PhD, Associate Professor, School of Nursing, University at Buffalo) on one of the terminated grants. This grant, Award No. 92615, is titled Peer Victimization and Risky Alcohol Use among Sexual Minority Youth: Understanding Mechanisms and Contexts. In this grant we investigate the impact of peer victimization (PV) on health outcomes among LGBQ+ youth. These youth experience significant health disparities, including higher risk for suicide, greater mental health symptoms, and riskier alcohol and other substance use behaviors compared to exclusively heterosexual youth. These disparities are due, in part, to the exposure to unique and chronic minority stressors targeting their sexual identities. The relationship between PV and adverse health outcomes has been well-established for heterosexual youth, but the role of PV on these outcomes when accounting for sexual minority stressors is understudied. In this grant, we seek a better understanding of the complex and unique factors that elevate and ameliorate harmful outcomes for LGBQ+ youth in

the presence of minority stress and PV. Our study is novel in that we are using a developmental lens to assess participants over an 18-month period during which data are collected using surveys administered every 6 months, daily reports collected over two 4-week bursts, and qualitative interviews with a targeted subsample. This research is vital to improving the public health of millions of American youth who identify as LGBQ+ thereby reducing economic burden related to healthcare costs for these youth as they mature into adulthood. We have recruited 325 participants, representing 81.3% of the target sample. To date, only 11.4% of these participants have progressed through all phases of study. Preliminary unpublished results from this study underscore the negative impact of PV on health outcomes among LGBQ+ youth and identify heterogeneity of risks among these youth based on their sexual identity. Interviews with these youth underscore the negative emotional and psychological impact of PV on LGBQ+ youth, while also identifying factors that protective against these poor outcomes. Results indicate that parental support, LGBQ+ friendly school climate, and receipt of care from educated and culturally competent health providers are critical factors to consider as targets for future interventions to improve the health and well-being of these youth.

Comparisons Across Administrations

19. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

20. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

21. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Research-Related Operations

22. Termination of this grant has halted recruitment of new participants and ongoing longitudinal data collection, thereby jeopardizing our ability to achieve the stated aims. We are currently in the fourth year of the grant award, and anticipated an additional year of direct costs funding, which would have allowed us to complete participant recruitment and the follow-up assessments necessary to achieve the stated aims. Our grant supports the salaries of three highly trained research staff, all of whom were to be terminated without any warning and without cause. This termination renders them immediately unemployed, resulting in their loss of benefits accrued over years of service in the State University of New York (SUNY) system. Furthermore, loss of these three staff members impedes our ability to conduct activities in coordination with our staff to close out the grant as per NIH requirements, as instructed in the termination notice (i.e., closing records, notifying participants, paying final bills, reconciling expenses, preparing data for analysis and archiving). Loss of the project data analyst would also disrupt dissemination and scholarship, thereby hindering our team's contributions to the research and scholarship central to the University at Buffalo's mission. Overall, our inability to complete the study represents a significant loss of investment already made by the NIH and the American taxpayers.

23. These terminations have forced the dean of our school to implement bridge funding to support our staff and compensate participants who have recently completed their assessments but were not compensated prior to receipt of the termination notice. Our school's capacity is limited to providing two weeks of bridge funds, after which our three staff members will be unemployed, preventing the completion of the project close-out. These staff were long-term SUNY Research Foundation employees and have been supported by our grant funding for

nearly four years. The sudden loss of employment with no due cause is economically and psychologically damaging to them.

Admissions, Training and Workforce Disruptions

24. The instability resulting from unanticipated grant terminations will affect the recruitment and retention of quality Ph.D. students in the School of Nursing and the University at Buffalo. Nursing Ph.D. students are required to participate in research as part of their program and a loss of the grant and the data that it would generate would adversely impact training opportunities. The inability to retain quality Ph.D. student research trainees will have continuing effects on the research capabilities of the University at Buffalo and will undermine the advancement of nursing science and public health.

Irreparable Harm

25. These termination notices have forced us and other researchers at the University at Buffalo and across the nation to abandon studies, miss deadlines, and/or lose key personnel. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

26. The termination of our grant and thousands of other NIH-funded grants across the nation will undermine and stagnate scientific progress to understand the nature of health disparities among LGBQ+ populations. Recent estimates indicate that 9.3% of the U.S. adult population is LGBQ+, and the numbers of adolescents identifying as LGBQ+ is higher now than any time in prior history. The terminations have broad implications for the future of LGBQ+ research and the health of significant numbers of Americans. The impact is unmeasurable and has implications that will be seen far into the future for today's LGBQ+ youth. The health and well-being of a sizeable and vulnerable segment of our population is in jeopardy.

27. Given the longitudinal and developmental nature of the current research, the study had the potential to contribute to prevention and intervention efforts to improve the health and well-being of millions who identify as LGBQ+ in our nation. Such breakthroughs would have advanced public health and will now not occur.

Conclusion

28. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

29. The termination of the NIH R01 grant has halted critical research investigating the impact of peer victimization on health outcomes among LGBQ+ youth, disrupting participant recruitment and data collection in the study's final year. The abrupt loss of funding has left three highly trained research staff unemployed without warning, preventing the completion of required closeout activities such as data reconciliation and analysis. The resulting instability has also jeopardized Ph.D. student research opportunities in the School of Nursing, undermining both immediate and long-term contributions to nursing science and public health.

30. Beyond institutional disruptions, this termination undermines scientific progress in understanding health disparities among LGBQ+ populations. With growing numbers of adolescents identifying as LGBQ+, this research had the potential to inform vital prevention and intervention strategies. The premature termination not only wastes prior NIH investments but also has long-term consequences for public health, leaving a vulnerable population without the

benefits of evidence-based policy and healthcare improvements. Many of these harms—particularly the loss of data continuity, personnel, and research momentum—are irreparable.

Amy Hequembourg, PhD

Date: 4-1-25

EXHIBIT A

National Institutes of Health
Office of Extramural Research

March 12, 2025

Amy Lagowski
Research Foundation for the State University of New York
Amy.Lagowski@buffalo.edu

Dear Amy Lagowski:

Funding for Project Number 1P50MD019473-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 19, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 22:17:03 -04'00'

Michelle G. Bulls, on behalf Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT B

Wshen7@buffalo.edu

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:31 PM
To: Wei Shen <wshen7@buffalo.edu>
Subject: Grant Termination Notification



3/21/2025

Wei Shen
State University Of New York At Buffalo
wshen7@buffalo.edu

Dear Wei Shen:

Effective with the date of this letter, funding for Project Number 5K01MH130270-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 8/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents [12]

supporting your claim.

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT C



3/21/2025

Mical, Alison
State University Of New York At Buffalo
alodojew@buffalo.edu

Dear Mical, Alison:

Effective with the date of this letter, funding for Project Number 5R01AA028810-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 26

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF BETHANY D. JENKINS

I, Bethany D. Jenkins, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Economic Development and Professor of Cell and Molecular Biology at the University of Rhode Island. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Vice President for Research and Economic Development and Professor of Cell and Molecular Biology at University of Rhode Island. As the Vice President for Research and Economic Development I help our community receive competitive federal awards that augment significant investments made by the State of Rhode Island in URI as our State's flagship land and sea grant university.

4. University of Rhode Island's mission is one as a student-centered research institution, that actively partners with other organizations globally and locally to advance knowledge and to develop

informed residents and leaders. URI is committed to high-quality education, community engagement, and solving the world's most important challenges. Situated on the traditional land and territories of the Narragansett Nation and the Niantic People, URI strives to create a diverse and inclusive environment for researchers, teachers, learners, and community members.

5. University of Rhode Island has three campuses throughout the state of Rhode Island, that serve approximately 14,000 undergraduate students and approximately 3,000 graduate students.

6. I am providing this declaration to document the impacts of NIH grant terminations on the University of Rhode Island.

Reliance on NIH Funding

7. In fiscal year 2024, University of Rhode Island received funding through the National Institutes of Health ("NIH") to support over 90 projects, totaling $22.1 M.

8. University of Rhode Island receives NIH grants across a variety of institutes encompassed within the NIH, including the National Center for Complementary and Integrative Health, , the National Institute on Aging, the National Institute on Alcohol Abuse and Alcoholism, The National Institute of Allergy and Infectious Disease, National Institute of Arthritis & Musculoskeletal & Skin Diseases, the National Institute of Biomedical Imaging and Bioengineering, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Environmental Health Sciences, the National Institute of General Medical Sciences, the National Institute National Institute of Neurological Disorders and Stroke, the National Institute of Nursing Research, the Office of the Director, and the Office of Research Infrastructure Programs.

9. The work done by University of Rhode Island on NIH funded projects provides education and training in Agriculture, Biology, Biomedical Engineering, Chemistry, Chemical Engineering, Civil Engineering, Computational Biology, Computer Sciences, Electrical Engineering, Health Sciences, Kinesiology, Mathematics, Mechanical Engineering, Public Health, Neuroscience, Nutrition, Nursing, Pharmaceutical Sciences, Physics, Psychology, Sociology, and other programs.

10. University of Rhode Island provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Rhode Island economy.

Typical Timeline and Processes for NIH Grant Awards

11. The Division of Research and Economic Development at University of Rhode Island works with researchers to submit grant applications and tracks grant applications and awards.

12. Based on my work as Vice President for Research and Economic Development, I have an understanding of the NIH grant process based on my 2 years in the role and 19 years as Principal Investigator managing federal awards.

Terminations of NIH Grants

13. Since March 21, the University of Rhode Island has had two NIH grants terminated.

14. The terminations received as of April 1 are attached hereto as Exhibits A and B.

15. These terminations will result in the loss of $3.7 million in research money to University of Rhode Island.

16. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs." In my 2 years as the Vice President for Research at University of Rhode Island, I have not seen this language previously used to cancel grants.

17. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, University of Rhode Island had not been given notice of any opportunity to submit any "corrected" grant

materials to align with agency priorities. Nor was University of Rhode Island provided with any updated "agency priorities" with which its research must align.

18. On March 20, NIH terminated Project Number 1R01 DA058994-01A1, Network-based study design, statistical, and modeling solutions for HIV among populations that use illicit substances: informing interventions and policy in real-world settings using existing data had been "hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(2). The terminated project is a transdisciplinary collaboration led by the University of Rhode Island with performance sites at Boston University, The New York University School of Medicine, the University of Chicago and Brown University. The terminated research is innovative and essential to advance HIV research by contributing to the investigation of causal mechanisms among networks of populations at high risk for HIV infection compounded by illicit substance use, specifically men at risk for HIV.

19. On March 21, NIH terminated ESTEEMED Scholars Program at the University of Rhode Island Project Number 5R25EB034489-02. The URI ESTEEMED program provides students from underrepresented backgrounds with the skills and resources necessary to pursue advanced education and degree programs in bioengineering and related disciplines. The goals of URI ESTEEMED program are (1) to develop a cohort of scholars who embody critical thinking, engineering design, and fundamental research skills that enable them to develop an early scientific inquiry and research mindset, and (2) to support the development of Scholars' STEM identity and self-efficacy through self-exploration, faculty and near-peer mentoring, academic and professional development advising, academic support and preparation, and positive research experiences. The impact on student achievement and the inclusive environment at URI will be hit particularly hard. Without URI ESTEEMED, several of our current trainees would have had to drop out of URI due to the lack of academic support the program provided and the stipend that allowed them to focus on their academics and research instead of working an outside job. The loss of URI ESTEEMED means that we will not have the resources to cultivate a community of diverse scholars on the same level and devalues the importance of the work the trainees have achieved

thus far. Furthermore, faculty mentors who volunteer their time and resources to mentor our trainees will not have the opportunity to work with such a diverse group of students under the support of the URI ESTEEMED program.

Comparisons Across Administrations

20. In prior years, terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

21. Each loss of support for grant funded staff and students is a significant impact on URI's budget. URI is in the process of trying to determine how and to what extent it can continue to support students, staff and faculty time that were supported by federal funds that were terminated

22. Use of internal funds to replace federally funded salaries prevents the use of these funds for any other purpose, including other planned improvements to our programs and research.

Conclusion

23. NIH grant terminations with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



Bethany Diane Jenkins

Date: 4/1/2025

EXHIBIT A

National Institutes of Health
Office of Extramural Research

March 20, 2025

Bethany Jenkins
University of Rhode Island
[redacted]

Dear Bethany Jenkins:

Effective with the date of this letter, funding for Project Number 1R01 DA058994-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 15, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 10:11:04 -04'00'

Michelle G. Bulls, on behalf of Pamela Fleming, Chief Grants Management Officer, National Institute on Drug Abuse
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT B

---------- Forwarded message ---------
From: **Jean** [redacted]
Date: Fri, Mar 21, 2025 at 12:33 PM
Subject: Fwd: Grant Termination Notification
To: Kate Barber <k[redacted]

Hi Kate,

Sorry for this news.

This letter is in regards to Samantha [redacted] project P11444 and P13130.

Kind regards,

Jean

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <[redacted]v>
Date: Fri, Mar 21, 2025 at 12:29 PM
Subject: Grant Termination Notification
To: [redacted]>

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

Jean [redacted]

University Of Rhode Island

[redacted]

Dear Jean [redacted]:

Effective with the date of this letter, funding for Project Number 5R25EB034489-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 5/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.**[8]***

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Mutema Nyankale, Chief Grants Management Officer, NIBIB

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

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Jean L [redacted]

EXHIBIT 27

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., Plaintiffs, v. ROBERT F. KENNEDY, JR., et al., Defendants.	No. 1:25-cv-_____

DECLARATION OF MARI OSTENDORF

I, Mari Ostendorf, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice Provost of Research of University of Washington. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Vice Provost for Research in the Office of Research at the University of Washington, a position I have held since 2021. As Vice Provost for Research, I have oversight over the pre-award process, reporting of institution-wide research statistics, and several research compliance offices. In addition, I oversee two major research units: the Applied Physics Laboratory and the Washington National Primate Research Center. Prior to holding this position, I served as Associate Vice Provost for Research in the Office of Research since 2017.

4. The University of Washington is the flagship university of the state of Washington. Since its founding in 1861, it has been a hub for learning, innovation, problem solving, economic development and community building. Driven by a mission to serve the greater good, our students, faculty and staff tackle today's most pressing challenges with courage and creativity, making a difference across Washington state—and around the world. As part of its mission, the UW engages in research and direct service, which frequently rely in whole or in part on federal financial assistance.

5. The University of Washington School of Medicine is dedicated to improving the general health and well-being of the public. In pursuit of its goals, the School is committed to excellence in biomedical education, research and healthcare. The School is also dedicated to ethical conduct in all its activities.

6. As the pre-eminent academic medical center in our region and as a national leader in biomedical research, we place special emphasis on educating and training physicians, scientists and allied health professionals dedicated to two distinct goals: 1) Meeting the healthcare needs of our region, especially by recognizing the importance of primary care and providing service to underserved populations; and 2) Advancing knowledge and assuming leadership in the biomedical sciences and in academic medicine.

7. The UW receives more federal research dollars than any other U.S. public university. In particular, funding from the National Institutes of Health is critical to UW's mission. In fiscal year 2024, UW received more than 1,220 NIH grants, totaling over $648 million. However, recent actions by NIH, including cancelling study sections, delaying grant renewals, and terminating grants, have severely impacted UW's ability to accomplish its mission. Because of NIH's actions in delaying and cancelling grant awards, UW is now facing funding disruptions

which are forcing it to furlough and potentially lay off research staff and faculty, cut admissions to graduate programs, including not taking any new undergraduate researchers in labs during the summer semester, and causing unprecedented budget uncertainty. These cuts have also led individual researchers to scale back their research or to limit their research to less complex experiments.

UW Relies on NIH Funding

8. As noted, UW currently has over 1,200 NIH grants. These grants come from 23 different funding institutes within NIH.

9. Through those NIH grants, UW funds over 3000 researchers (faculty, graduate students, and research staff).

10. NIH grants support research, education, and training, into project areas spanning a dizzying array, from biomedical engineering, to suicide reduction, to health equity, to protein design using artificial intelligence, diabetes, cancer treatments, kidney disease, and countless other examples.

Typical Timeline and Processes for NIH Grant Awards

11. The Office of Sponsored Programs at UW works with researchers to submit grant applications and tracks grant applications and awards.

12. As detailed elsewhere, NIH grant applications are evaluated by study sections, who determine whether a project has scientific merit. Applications are scored, and if a grant application receives a "excellent priority score", it will likely be funded.

13. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets,

a Notice of Award is issued confirming whether or not the grant will be funded after all administrative review steps are completed.

14. The process for competitive renewals is very similar.

15. The budget process at UW relies upon the regular NIH grant application submission, review, and approval cycle. Typically, we rely in grants being reviewed and scored within three to six months of submission and funding is generally awarded within nine to twelve months for meritorious grants.

16. Based upon those published NIH timelines, UW is able to make educated decisions around hiring research staff and graduate students. The regularity of the grant cycle is thus critical for UW in setting its budget.

Delays and Irregularities in the Processing of NIH Grant Applications

17. Since the Inauguration, UW has experienced unprecedented delays in the processing of NIH grant applications. NIH study sections and advisory councils have been canceled, delayed or otherwise not scheduled, and grant application scoring has been significantly delayed.

18. As of April 1, 2025, UW has more than 500 proposals awaiting NIH study section review.

19. As of April 1, 2025, UW has 54 proposals for $138 million in total funding requested that received fundable scores, awaiting NIH advisory council and Notice of Award.

20. As of April 1, 2025, UW has 76 proposals for $260 million in total funding requested with fundable scores that for which the NIH advisory council has met or voted electronically to approve a grant for funding, but the NOA has not yet been issued.

21. On top of that, UW is also experiencing significant delays in so-called non-competing or Type 5 renewals. These are grant awards for which NIH has issued an award for a given year (called the "award year"), with a commitment to fund further years (called "out years"), so long as the grantee demonstrates adequate progress. The out years typically require a new notice of award (NOA) after submission of a progress report (RPPR). This is generally pro forma, and unless the grantee gets nothing done or does not submit the progress report, the next year of funding is awarded. This decision is made by the NIH program officer without peer review. Type 5 NOAs are generally received at least one week (often more) before the start of the new budget period. There can be delays with a new administration or while on continuing resolution, however, the more common practice is to award them at 90% of the budgeted amount and then to increase to full budget once the FY budget is passed (assuming no major cuts to NIH).

22. As of April 1, 2025, UW has 73 overdue non-competing renewals totaling over $61 million that have yet to receive NOAs.

23. I want to highlight four important research centers that are at risk because of delays in the grants review and award processes at NIH. They are the Alzheimer's Disease Research Center (ADRC), the Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging, the joint UW/Allen Center "*A multimodal brain cell atlas and community resource of Alzheimer's disease and comorbid dementias," and* the Institute for Translational Health Science (ITHS), Three of these Centers are funded by the National Institute on Aging (NIA) and received excellent scores during their reviews in study section in the fall. Because the NIA Council did not meet as scheduled in the January, these large grants were not approved for award. They all end in March, April or May and would leave large research teams without support. The work being done by these

centers is longitudinal and lapse in funding will mean loss of critical cohorts that have been studied in some cases up to 40 years.

UW Alzheimer's Disease Research Center (ADRC)

24. The NIH-funded University of Washington Alzheimer's Disease Research Center ("ADRC"; P30 AG066509) is the main platform for Alzheimer's disease research in Washington state. Alzheimer's disease processes start 15 years before symptoms occur and run their course across decades. Serious study of Alzheimer's disease biology and treatment requires following research participants for years, characterizing their trajectories with genetic, cognitive, imaging, and biomarker tests, and doing detailed biological studies on brain tissue after death. The cycle of recruitment, long term evaluation and brain donation is the cornerstone of research that leads to effective new drugs. The Alzheimer's Disease Centers program maintains a stable network of 35 ADRC Centers and supporting programs that cooperate to study Alzheimer's disease and related disorders in a standard, long term way. The resulting data is pooled for widespread scientific analysis. The University of Washington ADRC has been continuously funded for 40 years and is one of the leading centers. We contributed key research identifying genetic causes of Alzheimer's disease and continue to study tissue and data from our families with ever more powerful techniques. We focus on the biology of degenerative dementia and the factors that counter degeneration and dementia. Many other studies depend on our UW ADRC and its sister ADRCs for participants and biospecimens like blood, spinal fluid, and brain tissue, to advance their work more powerfully and less expensively. In addition, the ADRC is part of the UW Medicine Memory and Brain Wellness Center that ensures state of the art care for patients with memory loss and dementia. As disease-modifying treatments,

like lecanemab and donanemab are now available, the ADRCs are becoming more tightly connected to their clinics.

25. Currently, the UW ADRC is in its renewal cycle, with a fundable score, but unable to move forward into the next five years of funding without NIA Advisory Council action. Lapse of funding for the ADRC, which appears likely, will mean serious interruption of the longitudinal research, loss of key personnel who have developed expertise over years of devoted service, and loss of availability of key resources, like appropriately curated brain tissue, that are essential for the affiliated studies. For example, we have a major project with the Allen Institute for Brain Science (U19 AG060909) that depends on our brain tissue. NIH funding means stability and longevity of resource centers like ours and is irreplaceable.

Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging

26. I would like to highlight our NIA P30 Nathan Shock Center of Excellence (NSC) in the Basic Biology of Aging and its companion training grant (T32) the Biological Mechanisms of Healthy Aging (BMHA) Training grant. We submitted the renewals last year and the NSC received an impact score of 15 and the BMHA received an impact score of 13. These scores reflect the outstanding impact the NSC and BMHA continue to have on aging research in both scientific discovery and training the next generation. Both grants have been "recommended for funding" but, like the ADRC, are awaiting final decision at the January NIA Advisory Council that has been postponed. Funding for the NSC and BMHA ends in May and April 2025, respectively.

27. The UW NSC is one of eight NSCs and is the longest running one in the country (over 30 years). It provides critical funding for pilot programs for junior investigators and collaborative projects with other centers from around the country to provide access to state-of-the-art expertise in protein phenotypes, metabolite phenotypes, invertebrate models and artificial

intelligence to understand the basic mechanisms of human aging. Three of these four cores have been part of the NSC for 15 years and the newer AI core is a world leader in state-of-the-art AI tools for health and medicine. They have ongoing collaborations both within the UW and across the country working to establish new biomarkers, identify new biological mechanisms, and testing new interventions to improve health in the aging population. Without timely renewal of the NSC these ongoing studies will be jeopardized, and our core laboratories face the risk of losing staff with critical expertise. The BMHA is a rigorous training program closely affiliated with the NSC that currently supports 6 predoctoral and 6 postdoctoral fellows. The training program not only includes laboratory-based research in aging biology, but career development programs, mentoring, and networking opportunities to help prepare the next generation of scientists to become independent scientists in basic and translational aging biology. A delay in renewal of the BMHA runs the risk of not only losing this current cohort of trainees but also risks dismantling the training program and staff. These are both critical centers to the UW infrastructure and educational programs and, with the ADRC, are key drivers of the international recognition of the UW as a leader in driving new treatments for improved health with age. We are extremely anxious about the impact of the ongoing delays at the NIH on their futures.

U19 UW/Allen Institute "*A multimodal brain cell atlas and community resource of Alzheimer's disease and comorbid dementias*"

28. The goal of this U19 Center Collaboration with UW and Allen Institute for Brain Science is to build a national brain tissue and data resource to stimulate cutting edge research in Alzheimer's Disease (AD). A unique aspect of this project is the tight integration with the NIH BRAIN Initiative's flagship Cell Census projects, which has allowed us to rapidly build on cutting edge advances in the BRAIN Initiative and use them to understand Alzheimer's disease in unprecedented detail, and also to disseminate these advances to the larger AD research and medical

communities. Over the first five years of this center, we developed techniques and tools to optimally preserve and characterize human brain tissue from the UW ADRC and affiliated studies. The Center has produced advances in our ability to manage, process, and analyze brain tissue for AD/ADRD that have led to substantial progress in our understanding of the cell type basis of these diseases. This has led to an openly accessible highly multimodal data resource that serves as a reference for the entire field of human AD research. The goal of this center is to identify early vulnerable cells in AD using cutting edge genomics tools and to identify potential therapeutic strategies to protect those cells. The renewal extends this study to build a national network of ADRCs to adopt these cutting-edge techniques across multiple cohorts to build this resource around Alzheimer's Disease related dementias (ADRD) including Lewy body dementia, Parkinson's disease, vascular dementia, etc. The renewal integrates new technology, including multimodal spatial genomics applications, to continue to understand AD and AD/ADRD mechanisms. The renewal proposes to develop a neuropathology consensus panel to improve existing or develop new ways to diagnose and differentiate AD and AD/ADRD. A critical aspect of this work is that all of the data is openly accessible, and has already served as a resource for many highly impactful studies across the US and internationally (https://portal.brain-map.org/explore/seattle-alzheimers-disease) with more than 29,000 users. The platform paper for SEA-AD was published last year (https://www.nature.com/articles/s41593-024-01774-5) and this work has been featured in local and national media (reaching over 70M people). But all of this work is now jeopardized by NIH's funding delays.

Institute of Translational Health Sciences (ITHS)

29. A partnership between the University of Washington, Fred Hutchinson Cancer Center, Seattle Children's, and regional institutions ITHS promotes the translation of scientific

discovery to clinical practice by fostering innovative research, cultivating multi-disciplinary research partnerships, and ensuring a pipeline of next generation researchers through robust educational and career development programs throughout the Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI) region.

30. One example of the innovative work performed at ITHS' is the Gene & Cell Therapy Lab's (GCTL) acceleration of medical discoveries to clinical environments through partnerships. One such partnership involved a biopharmaceutical company that developed a therapy to treat advanced ovarian cancer, called UltraCAR-T Cell therapy. Scientists in the GCTL worked with the company to transfer the technology so that the product could be made quickly and effectively. A separate unit of ITHS, the Translational Research Unit, conducted the rigorous clinical trials necessary to advance the technology towards a clinical use.

31. ITHS supports collaboration between primary care practices and academic researchers that improves the health and well-being of patients in their communities and enhances primary care clinical practice through its WWAMI Practice and Research Network. This practice-based research network, known as the WPRN, spans 34 organizations and over 90 clinics in the five-state WWAMI region.

32. ITHS is supported by a $10.5 million annual grant from NIH. UW did not receive an expected NOA generated by a non-competing renewal for ITHS on March 1, 2025. Without funding for over thirty days, UW was forced to institute staff reductions, furloughs, and elimination of positions at ITHS.

Terminations of NIH Grants

33. Since February 28, UW has had at least seven NIH grants terminated on which a UW researcher was the prime grantee.[1] UW has also had multiple grants terminated in which a UW researcher is a subgrantee.

34. The prime grantee terminations received as of April 1 are attached hereto as Exhibits A-G.

35. These terminations will result in the loss of over $2.9 million in research money to UW.

36. The termination notices do not explain why the grants are being terminated, instead claiming that the research no longer "effectuates agency priorities." Of course, these grants were initially approved through NIH's rigorous process—some as recently as last year, while others have been continually funded for multiple years—and NIH failed to explain what changed. In my experience, I have never before seen NIH cancel a grant because it supposedly no longer comports with agency priorities.

37. The termination notices claim that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to the terminations, UW was not given any opportunity to submit revised grant materials to align with agency priorities, nor were grantees even given an opportunity to explain what their work was and how it might align with agency priorities. Nor was UW provided with any updated definition of "agency priorities" with which its research must align.

38. These grants all funded amazing work by UW researchers. For example, NIH terminated Grant No. 5R01MD017573-03 to UW Professor Emily Dworkin. That grant funded a groundbreaking study on the impact of anti-LGBTQ policies on sexual minority health across the

[1] This does exclude one grant that NIH terminated and then subsequently reinstated.

nation. Dr. Dworkin's study sought to understand the causes of disproportionately high rates PTSD and other mental health issues among sexual minority women who have experienced sexual assault with an eye toward understanding how the political and social environment affects people, and, consequently, how changing people's environments can improve mental health. This was year three of the project, meaning that significant work had already been done—which will now be wasted if funding is not restored.

39. In its cancellation letter, NIH wrote: "This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs." Given that Dr. Dworkin's research sought to understand, and hopefully address, significant mental health issues among sexual minority women, it is hard to see how NIH could possibly have concluded that her research was unlikely to contributed to public health.

40. As another example, NIH terminated Grant No. 1F31 AI181431-01A1. That grant, to UW graduate student Gregory Zane, funded research into prophylactic antibiotic treatment for Chlamydia trachomatis, a bacterium that "causes roughly 128 million sexually transmitted infections globally each year." And, in light of "concerns of antibiotic resistance," Zane's research also sought to assess whether "CT vaccination a cost-effective prevention strategy compared to current screen-and-treat practices in the United States[.]" "To answer these questions," the NIH

grant funded research into "the frequency and factors associated with antibiotic use among" men who have sex with men to "predict the 50-year impact of national rollout of a theoretical vaccine."

41. But yet again, the termination letter declared that this research—which was approved just eight months ago—"no longer effectuates agency priorities." According to the letter, "[i]t is the policy of NIH not to prioritize research activities that focuses [on] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment." NIH otherwise offered no explanation for this about-face.

42. In addition to these outright terminations, I am also aware of at least two instances (so far) in which a UW researcher lost funding because of NIH's new decision to no longer fund Diversity Supplements. Diversity Supplements are workforce development grants meant to increase diversity in the scientific profession by providing training, mentorship and career development opportunities to individuals from underrepresented populations.[2]

43. However, my understanding is that NIH has recently decided to cancel NOFOs for Diversity Supplements, meaning that researchers who have applied for, and in many cases, already received funding under a Diversity Supplement are now getting their funding pulled.

44. In one case, a research scientist at Seattle Children's Hospital was awarded a $177,553 diversity supplement grant to support a study on lupus aimed at developing new targeted therapies for the treatment of lupus. However, on January 28, NIH sent an email cancelling the researcher's grant with no explanation.

[2] NIH has defined diversity broadly, to include not only "[i]ndividuals from racial and ethnic groups that have been shown by the NSF to be underrepresented in health-related sciences on a national basis," but also "[i]ndividuals with disabilities," and "[i]ndividuals from disadvantaged backgrounds," including those who have experienced homelessness, who were in foster care, who experienced poverty, or who are from rural areas. https://grants.nih.gov/grants/guide/pa-files/pa-20-222.html.

45. In another case, a UW postdoctoral fellow lost their funding because a diversity NOFO was cancelled. This postdoctoral fellow had received funding under a K99 grant, which help post-docs transition to faculty roles. The K99 phase funds 1-2 years of postdoc, and then, if the researcher gets a faculty job, they receive 3 years of R00 funding at the institution where their faculty job is located (often a different institution). This researcher had received a $132,381 K99, funded in response to a Diversity NOFO, to study the impact of air pollution on Alzheimer's disease and related dementias. However, when UW submitted the researcher's R00 transition application, it was rejected by NIH within a few hours. The email rejecting the application said, merely: "Because your application was in response to a Diversity NOFO that has been expired and is no longer a priority to the NIH, we will not be able to award the R00 phase of this grant."

46. In other words, this researcher had her funding cut off mid-stream not because of anything she had done or failed to do but because she had applied for a grant through a previously approved funding mechanism designed to increase participation of diverse individuals in research careers.

Impact on Institutional Operations

47. The failure of NIH to communicate deviation from the normal funding application cycle for reviews and approval of funding means that research team which often plan grant applications years in advance to maintain necessary funding to support their research teams are left without consistent funding and in some cases are needing to furlough or layoff research team members.

48. We have paused some new hires whose research programs depend on timely NIH awards to conserve funding to allow us to support research staff that would normally be funded on NIH grants. This includes several faculty searches that were underway for the 2024–2025

academic year, which had already been advertised and in some cases multiple candidates had already been interviewed on campus.

49. UW has also been forced to cut admissions to graduate programs across the University. Depending on the department, the cutbacks in admissions have ranged between 25 and 50%.

50. Moreover, the terminations, delays, and unprecedented disruptions in funding have had a profoundly negative effect on morale University wide. Faculty and staff don't know if their funding will be cut, if their research will be terminated, whether they will be able to attend conference, or even whether they will continue to have jobs. The stress of these funding disruptions is palpable, and even if I cannot measure it, I am certain it has negatively affected our mission as a University. Research staff that are stressed about losing their jobs on a daily basis are not able to focus their full creative energy on innovation and discovery.

Irreparable Harm

51. The delays have disrupted ongoing research, as well as setting back UW for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the interim measures being taken by UW to keep certain research going. UW has had to make decisions about which of these valuable programs to continue with these limited funds.

52. Some of these studies involve clinical trials for life-saving medications or procedures, and their closure would endanger the lives of patients. The Department of Neurology has had to provide interim funding to ensure patient safety in a clinical trial of sleep apnea treatment for stroke patients. Department of Medicine was not able to enroll any patients in a clinical trial for HIV patients.

53. At bottom, NIH's actions have fundamentally undermined UW's mission to pursue scientific research. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Executed this 1st day of April 2025, in Seattle, Washington.



MARI OSTENDORF
Vice Provost of Research
University of Washington

Exhibit A

Outlook

FW: Grant Termination Notification | A160406 [5UG4LM013725-04]

From Office Of Sponsored Programs <osp@uw.edu>
Date Fri 3/21/2025 3:22 PM
To Carol Rhodes <carhodes@uw.edu>
Cc Jenny Muilenburg <jmuil@uw.edu>

Hi Carol,

MOD47947 was created for this, assigned to you and is in OSP Setup status.

Best,

Dianna

From: Michael Snow <mi esnow@uw.edu>
Sent: Friday, March 21, 2025 10:41 AM
To: Of ce Of Sponsored Programs <osp@uw.edu>
Cc: Ariadna A. Santander < limus@uw.edu> Amanda C Snyder <acs229@uw.edu> Josy S Combs <combsj3@uw.edu>
Subject: FW: Grant Termination Noti cation A1 040 5UG4LM013725-04

Hi Dianna,

Another NIH termination letter, please set this up as a MOD to AWD-005078. I believe there are subawards.

Than s,
Mi e

MICHAEL SNOW / Manager, Proposals and Awards Team Gold , Of ce of Sponsored Programs / 20 .221.0553

From: Jonathan N. Geraghty <geraghti@uw.edu>
Sent: Friday, March 21, 2025 10:30 AM
To: Ariadna A. Santander < limus@uw.edu> Michael Snow <mi esnow@uw.edu>
Subject: FW: Grant Termination Noti cation A1 040 5UG4LM013725-04

Hi Ari / Mi e:

I must have received this because I was listed as AOR at some point.

A1 040 5UG4LM013725-04

Let me now how I should proceed.

Jon

OSP contacts: https://www.washington.edu/research/contact-us/
Jonathan Geraghty Compliance Analyst UW Of ce of Sponsored Programs 20 - 85-4842 geraghti@uw.edu

From: Bulls, Michelle G. NIH/OD E <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:30 AM
To: Jonathan N. Geraghty <geraghti@uw.edu>
Subject: Grant Termination Noti cation



3/21/2025

Jonathan Nicklen Geraghty
University Of Washington
geraghti uw.edu

Dear Jonathan Nicklen Geraghty:

Effective with the date of this letter, funding for Project Number 5UG4LM013725-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 5/1/2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to

d

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Andrea Culhane, Chief Grants Management Officer, NLM
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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1 https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

2 2 C.F.R. 200.341 a 45 C.F.R. 75.373

3 *Bennett v. New Jersey*, 470 U.S. 32, 38 1985 .

4 NIH Grants Policy Statement at IIA-1.

5 *Id.* at IIA-155.

__ NIH Grants Policy Statement at IIA-15 .

7 *See* 2 C.F.R. 200.343 2024 .

8 2 C.F.R. 200.341 c 45 C.F.R. 75.373 c

9 *See* 45 C.F.R. 75.374.

10 See 42 C.F.R. Part 50, Subpart D

11 11 *Id.* 50.40 a

12 12 *Id.* 50.40 b

Exhibit B

Emily R Dworkin

From: Office Of Sponsored Programs <osp@uw.edu>
Sent: Friday, March 21, 2025 3:01 PM
To: Carol Rhodes
Cc: Emily R Dworkin
Subject: FW: Grant Termination Notification

Categories: Blue

Hello Carol,

MOD47944 has been created for this, assigned to you and is in "OSP Setup".

Best,

Dianna

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:30 AM
To: Office Of Sponsored Programs <osp@uw.edu>
Subject: Grant Termination Notification



3/21/2025

Rhodes, Carol
University Of Washington
osp@uw.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 5R01MD017573-03 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 12/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the

time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit C



March 18, 2025

Carol Rhodes
University of Washington
osp uw.edu

Dear Carol Rhodes:

Effective with the date of this letter, funding for Project Number 1F31 AI181431-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/16/2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to d

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S
Digitally signed by Michelle G. Bulls -S
Date: 2025.03.18 09:26:19 -04'00'

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit D



03/20/2025

Lester Warnac Villaflor
UNIVERSITY OF WASHINGTON
gcsfund uw.edu

Dear Lester Warnac Villaflor:

Effective with the date of this letter, funding for Project Number 5R01LM013301-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2023, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 16:19:56 -04'00'

Michelle G. Bulls, on behalf of Andrea Culhane, Chief Grants Management Officer,
National Library of Medicine
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit E



March 12, 2025

Carole Rhodes
University of Washington
carhodes uw.edu

Dear Carol Rhodes :

Funding for Project Number 1G13LM014426-01 is hereby terminated pursuant to the 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 15, 2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 23:15:18 -04'00'

Michelle G. Bulls, on behalf Andrea Culhane, Chief Grants Management Officer, NLM
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Exhibit F

UW-AOR on behalf of Tracking Grants.gov AOR emails via UW-AOR
uw-aor@u.washington.edu
[UW-AOR] Grant Termination Notification
Friday, March 21, 2025 9:38:52 AM
image001.jpg
image002.png
ATT00001.txt



3/21/2025

Rhodes, Carol
University Of Washington
uw-aor u.washington.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 1R21AI183907-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/10/2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to d

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9]

See 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Exhibit G



March 20, 2025

Carol Rhodes
University of Washington
uw-aor u.washington.edu

Dear Carol Rhodes:

Effective with the date of this letter, funding for Project Number 1R01 TW012904-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 9, 2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 17:04:13 -04'00'

Michelle G. Bulls, on behalf of Bruce Butrum, Chief Grants Management Officer, Fogarty International Center
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 28

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., Plaintiffs, v. ROBERT F. KENNEDY, JR., et al., Defendants.	No. 1:25-cv-_____

SUPPLEMENTAL DECLARATION OF MARI OSTENDORF

I, Mari Ostendorf, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice Provost of Research of University of Washington. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Supplemental Declaration in support of the States' Motion for Temporary Restraining Order.

3. On April 1, I signed a declaration in which I testified about nine separate NIH grant terminations received by UW researchers.

4. On April 2, in a single day, UW researchers received at least three more NIH grant terminations.

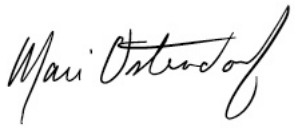
5. In one case, NIH terminated a K99 grant (awarded to postdoctoral scientists pursuing research careers) under the Maximizing Opportunity for Scientific and Academic Independent Careers program. In another, NIH terminated a grant under the Research Education Program, a program designed to support programs that enhance diversity in the scientific research

field. And in the third, NIH terminated an F31 grant under the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research.

6. In each case, the only explanation NIH gave for these terminations is that they were "due to changes in NIH/HHS priorities." The termination notices are attached hereto as **Exhibits H-J**.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Executed this 2nd day of April 2025, in Seattle, Washington.



MARI OSTENDORF
Vice Provost of Research
University of Washington

Exhibit H



[EXTERNAL]

From: UW-AOR <uw-aor-bounces@mailman13.u.washington.edu> **On Behalf Of** Tracking Grants.gov AOR emails via UW-AOR
Sent: Wednesday, April 2, 2025 10:51 AM
To: uw-aor@u.washington.edu
Subject: [UW-AOR] NIGMS Funding Update

Re: K99GM141364-02

Dear Rhodes, Carol,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

Exhibit I

From: Office Of Sponsored Programs
To: Carol Rhodes; Amanda C Snyder
Cc: Adelia Yee
Subject: FW: NIGMS Funding Update
Date: Wednesday, April 2, 2025 11:09:11 AM

Hi,

Here is the 3rd one.

Dianna

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 11:01 AM
To: Office Of Sponsored Programs <osp@uw.edu>
Subject: NIGMS Funding Update

Re: F31GM155953-01

Dear Carol Rhodes,

As Business Official for the above referenced award (PI FERNANDO BANALES MEJIA), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

Exhibit J

From: Office Of Sponsored Programs
To: Carol Rhodes; Amanda C Snyder
Cc: Adelia Yee
Subject: FW: NIGMS Funding Update
Date: Wednesday, April 2, 2025 10:32:24 AM

Good Morning,

Please see the notice below.

Dianna

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 10:15 AM
To: Office Of Sponsored Programs <osp@uw.edu>
Subject: NIGMS Funding Update

Re: GM086304-14

Dear Rhodes, Carol,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Postbaccalaureate Research Education Program (PREP)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 29

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF DOROTA A. GREJNER-BRZEZINSKA

I, Dorota Grejner-Brzezinska, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice Chancellor for Research at the University of Wisconsin-Madison ("UW-Madison"). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UW-Madison staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Vice Chancellor for Research at the University of Wisconsin-Madison, a position I have held since 2024. In this role, I have responsibility for overseeing the university's research enterprise with more than $1.7 billion in annual research expenditures. My office also includes administration of 20 cross-campus research and service centers. The mission of the Office of the Vice Chancellor for Research is to advance excellence in research and scholarship,

to support our multidisciplinary research centers and institutes, and to provide campus-wide administrative infrastructure to support and advance the research enterprise. Prior to holding this position, I was the Vice President of the Office of Knowledge Enterprise, Associate Dean for Research in the College of Engineering, and a Professor of Civil, Environmental and Geodetic Engineering at The Ohio State University. At Ohio State, I also served as senior vice president for corporate and government partnerships, focusing on growing research talent and helping launch new research institutes and centers. I have mentored 16 doctoral students and secured nearly $39 million in research funding for my own research, which is centered on GPS, the Global Positioning System. My laboratory developed the first fully digital and directly geo-referenced Airborne Integrated Mapping System, combining high-resolution digital, aerial camera images with GPS and inertial technology. I have served on the President's Council of Advisors on Science and Technology, and was appointed to the National Science Board in 2023. I am also a fellow of the American Association for the Advancement of Science, the Institute of Navigation, and the Royal Institute of Navigation and member of the National Academy of Engineering. Additionally, I serve as principal investigator of the National Science Foundation's Engineering Research Visioning Alliance.

4. UW-Madison is the flagship university of the University of Wisconsin System. The University of Wisconsin System's statutory mission, as set forth in Wis. Stat. § 36.01(2), is:

> to develop human resources, to discover and disseminate knowledge, to extend knowledge and its application beyond the boundaries of its campuses and to serve and stimulate society by developing in students heightened intellectual, cultural and humane sensitivities, scientific, professional and technological expertise and a sense of purpose. Inherent in this broad mission are methods of instruction, research, extended training and public service designed to educate people and improve the human condition. Basic to every purpose of the system is the search for truth.

5. UW-Madison is composed of 13 schools and colleges and, as of the Fall of 2024, enrolls over 52,000 students and employs over 27,000 faculty and staff.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections and advisory council meetings. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation in which grant proposals that had previously been reviewed positively have remained unfunded indefinitely. These are grant applications that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given an overall impact score and, generally, a percentile rank (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. Percentile ranks are based on an application's overall impact score in comparison with other applications reviewed by the same study section in a series of past meetings. Grant paylines are set by particular NIH Institutes/Centers (IC).

7. The NIH meeting blockade severely impacts the UW-Madison by delaying or potentially removing support for critical research into diseases and disorders that affect human health and quality of life. Laboratories engaged in this vital research will be disrupted by these delays, hindering scientific progress. If research is halted, it will be extremely difficult to restart due to the absence of dedicated and knowledgeable scientists and well-tooled scientific facilities. Diminished NIH support for research is also likely to reduce the future scientific workforce if trainee positions go unfunded and consequently unfilled. As such, delay or reduction of NIH funding will not only affect science in the present day, but compromise scientific progress in future generations.

8. Approximately one third of sponsored research at UW-Madison is awarded by the NIH. For this reason, even weeks of delays in funding result in considerable budgetary reductions, and the impact is expected to compound rapidly. Our institution has begun implementing strategic cost reductions, and as these grow the advancement of science will surely be negatively impacted.

Reliance on NIH Funding

9. In fiscal year 2024, UW-Madison received direct funding from the National Institutes of Health ("NIH") to support 588 projects, totaling $404,722,816.95.

10. UW-Madison receives NIH grants across a variety of institutes encompassed within the NIH, including Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Child Health and Human Development, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on

Minority Health and Health Disparities, National Library of Medicine, and the Office of Data Science Strategy.

11. Through those direct NIH grants, UW-Madison funds 4,942 researchers and staff.

12. The work done by UW-Madison on NIH-funded projects provides scientific education and research training in all areas of medical and health sciences, biology, public health, biochemistry, psychology, and other disciplines.

13. UW-Madison provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Wisconsin economy. For instance, more than 35,000 engineering, medicine, nursing and pharmacy graduates live in the state.

Typical Timeline and Processes for NIH Grant Awards

14. The Office of Research and Sponsored Programs at UW-Madison works with researchers to submit grant applications and tracks grant applications and awards.

15. I have an understanding of the NIH grant process based on my current work as Vice Chancellor for Research at UW-Madison and previous work as Vice President of the Office of Knowledge Enterprise and Associate Dean for Research in the College of Engineering at Ohio State University. My experience in those roles spans 7.5 years combined.

16. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given an overall impact score that reflects this scientific merit. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors as every institute or center, sometimes referred to as an "IC," is different. Some ICs publish paylines, meaning the percentiles of grants they will fund, and some do not. Published paylines generally range from 8-20%. Most of the standing study section reviews result in an overall impact score and percentile for each proposal, but many others will only result in an overall impact score and not a percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives.

18. After the study section meeting, grant applications and corresponding overall impact scores and/or percentile ranks are sent to an IC's "advisory council" for the second stage of NIH review, where the ultimate decision on whether to fund the grant is made. After the advisory council meets, a Notice of Award is issued if the grant will be funded.

19. The process for competitive renewals of NIH grants is very similar.

20. The budget process at UW-Madison relies upon the NIH grant application, review, and approval cycle. Historically, we have used a range of 4-6 months from submission for the review and scoring process to be complete. This general timeline supports sound planning for continuity of funding at the project level, which in turn flows upwards to institution-wide budgetary planning.

21. Once a grant receives a Notice of Award, UW-Madison is able to ascertain whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

22. Since late January 2025, UW-Madison has seen an unusual number of delays in the processing of NIH grant applications. Study sections and advisory councils have been

delayed, canceled, or otherwise not scheduled, and grant application scoring has been significantly delayed, creating a great deal of inefficiency in this process.

23. UW-Madison has not received formal notice of changes for many of these grants. For others, UW-Madison has received only a notification that proposals are paused or under review.

24. As of March 31, 2025, the University of Wisconsin-Madison has 829 direct proposals and 423 subaward proposals pending NIH review. These proposals, submitted since January 2024, request a total of $1,876,612,449 in direct NIH funding and $249,508,887 in incoming NIH subaward funding.

Terminations of NIH Grants

25. I am aware of four NIH grants to UW-Madison having been terminated since March 21, 2025. The total amount of funding anticipated under these awards was $25,149,959. Of that amount, $12,631,870 has not been disbursed to UW-Madison.

26. The terminations that I am aware of UW-Madison having received as of March 31, 2025 are attached hereto as Exhibits A - D.

27. These terminations will result in the loss of an anticipated $12,631,870 in research funding to UW-Madison.

28. The termination documentation for these grants has included statements regarding the lack of necessity for the research or unsubstantiated statements indicating a lack of scientific merit and other value. In most cases, the termination documentation noted that the research no longer "effectuates agency priorities."

29. Those termination notices that referenced the potential for corrective actions stated that there is no corrective action that can be taken to ensure the grant aligns with agency

priorities. However, prior to receipt of the termination, UW-Madison had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was UW-Madison provided with any updated "agency priorities" with which its research must align.

30. NIH Project 5R01AI158463 (Infectious Disease Research Grant), an R01 grant awarded to UW–Madison's Kirchdoerfer lab, focuses on investigating the molecular mechanisms of SARS-CoV-2 replication, specifically examining the functions of the virus's polymerase complex. The project aims to provide foundational insights into how multiple protein subunits contribute to coronavirus genetic replication, essential knowledge for developing effective antiviral therapeutics. Significant outcomes achieved include rapid publication of research findings, open sharing of structural data, and identification of critical viral components—such as the SARS-CoV-2 nsp14 exonuclease—that play roles in viral replication and antiviral drug resistance. Benchmarks reported through regular Research Performance Progress Reports (RPPRs) include timely publication of findings and sharing of structural data, compliance with NIH requirements, and substantial investment in core microscopy facilities explicitly supporting this research. The unexpected termination disrupts ongoing experiments on drug resistance mechanisms and halts crucial research activities, adversely affecting laboratory personnel and undermining public health preparedness against future coronavirus threats.

31. NIH Project 1P01AI165077-01 (PanCorVac – Center for Pan-Coronavirus Vaccine Development), a Program Project (P01) grant, established the PanCorVac Center at UW–Madison, aiming to develop protein-based vaccines effective against multiple coronavirus variants and future pandemic threats. The research has demonstrated significant scientific progress, including successful development and early animal testing of promising vaccine

candidates, resulting in peer-reviewed publications validating robust immune responses. The Center has collaborated with multiple subrecipient institutions and conducted comprehensive preclinical studies designed to move candidate vaccines toward human clinical trials. Reported benchmarks include completed testing of vaccine candidates in animal models, seven peer-reviewed publications, and substantial data generation to support translational research efforts to benefit people.

32. NIH Project 5R01MD018751 (Minority Health and Health Disparities Research Grant), an R01 grant awarded to Dr. Elliot Tebbe in UW-Madison's School of Nursing and Dr. Stephanie Budge in the School of Education, aims to identify essential components of social support that address known mental health disparities (e.g., anxiety, depression, suicidality) among transgender and nonbinary people, to develop and validate a new measure of social support for this population for use in future research and clinical settings, and to determine the protective effects of social support on mental health over time. Significant achievements in the progress of this grant prior to termination (from August 2024 to March 2025) included hiring all members of the research team (14 personnel in total) and beginning work on the development of an innovative data collection tool to capture intensive data on daily social experiences as part of project set up. The researchers were also nearing completion of a systematic review of the scientific literature on social support, and had completed qualitative interviews with national community leaders on community social support structures and strategies. This grant was terminated at the start of Year 2, with an anticipated four years remaining on the award. Despite the significant process made in a shortened Year 1 timeframe as reported in the Research Performance Progress Report (RPPR), the termination of this grant will eliminate the support already committed to graduate students, research staff, and infrastructure critical to the research.

33. NIH Project P01HD109850 (Child Health and Human Development Extramural Research), a P01 grant, was awarded to Dr. Megan Moreno and Dr. Ellen Selkie in the Department of Pediatrics, and Dr. Christopher Cascio in the School of Journalism and Mass Communication. The grant involves three independent projects and two university research cores. This grant's three projects all address a major health issue in America: the impact of media on adolescent physical and mental health, health behaviors, and brain development. This research program is the largest endeavor of its kind, with a goal of recruiting four hundred youth from across Wisconsin; the researchers had already recruited more than three hundred. Thus far, team members have presented preliminary findings from their ongoing longitudinal study, including 17 abstracts accepted across seven different local, national, and international conferences. The researchers have published one paper and a second is under review. Additionally, the project has helped uncover preliminary findings showing that self-generated content on social media is associated with increased ventromedial prefrontal cortex (VMPFC) activity compared to other-generated content (e.g., peer generated). This brain activity is associated with increased health (i.e., physical activity) and decreased risk (i.e. alcohol use) behaviors. The finding suggests that sharing personal information on social media integrates into adolescents' attitudes and actions and supports one mechanism that may underlie how self-posts influence behavior. Additionally, through a variety of approaches, including cyberethnography and criterion-based coding, the researchers have begun providing a rich picture of adolescent life online, particularly among middle schoolers, and its health and well-being correlates.

Comparisons Across Administrations

34. UW–Madison has never experienced this volume of unexplained delays or procedural breakdowns, including under both Democratic and Republican administrations.

35. Noncompetitive renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

36. The current approach is, in our experience, without precedent.

Impact on Institutional Operations

37. The uncertainty stemming from delays and cancellation of study sections makes both near- and long-term budgetary planning especially difficult. The workforce in support of research must align with available funding. Due to unpredictability regarding the extent, timeline and nature of diminished support, UW-Madison lacks the information necessary to make timely decisions necessitated by the change in NIH funding practices. UW-Madison anticipates losing well-trained employees from the research enterprise in the coming months; without clarity around future research support needs, rebuilding these human resources in the future will be costly and challenging. The productivity of researchers has already been discernibly impacted by discontinuity in funding and the time and effort required for managing communications and planning in this highly ambiguous period. While this is not quantifiable at this time, this lost work is a real cost. Similarly, facilities costs and operational support of research, including administrative and compliance support, will not be able to continue to be supported at the same level as grant funding is delayed or reduced. The institution is evaluating various scenarios, attempting to evaluate financial risk, with very little visibility into the approaching NIH funding landscape. As the duration of this period of ambiguity extends, prudent financial management will necessitate actions that will have a long tail; these are likely to harm the institution's fiscal health and make a return to efficient and excellent support of research difficult.

38. Several shared research cores have seen significantly decreased usage due to grant uncertainty. Research cores provide vital services available to multiple researchers and require continued financial support through grant-funded user fees to serve their critical functions.

Admissions, Training and Workforce Disruptions

39. UW-Madison uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the doctoral student level.

40. Of those programs that have reported admissions offers for Fall 2025 thus far, the number of admissions offers for doctoral students has decreased by approximately 25% due to uncertainty over grant funding because of the delays in reviewing and awarding NIH grants and because of NIH funding halts.

41. Multiple programs that have extended admissions offers have needed to clarify to admitted students that continuous funding support throughout the course of their doctoral program cannot be guaranteed. Prior to this spring, 92% of doctoral programs at UW-Madison have been able to offer guaranteed funding for 4-5 years. This is an important mechanism for UW-Madison to be competitive for the most talented doctoral students who will perform cutting edge research that advances disease diagnosis and treatment, and who become the future STEM workforce of the U.S.

42. I am aware of two NIH T32 training grants that have received fundable scores and have been affected by review and award delays as of March 31, 2025. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas. If T32 grants are not awarded in a timely manner, trainees who would receive funding under them will not have access to funding support for training intended to prepare them for

careers that meet the health-related research needs of the U.S. UW-Madison does not have a readily available alternative source of funding to support such trainees.

43. This instability is affecting the recruitment of quality research trainees. The inability to recruit quality research trainees will have continuing effects on the research capabilities of UW-Madison, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

44. UW-Madison is increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

Irreparable Harm

45. The delays have disrupted ongoing research due to the uncertainties in the timing of study section and advisory council reviews, and created setbacks for research at UW-Madison going forward. Some researchers have been unable to commit to bringing on graduate students or maintaining current trainees due to funding uncertainty, and have been forced to consider abandoning studies that historically would have been expected to receive funding.

46. In many cases, there is no way to recover the lost time, research continuity, or training value once research is disrupted.

47. The grants that have been terminated have the potential to achieve results that would have advanced public health, depriving Americans of the benefits derived from biomedical research. For instance:

- NIH Project 5R01AI158463 (Infectious Disease Research Grant) could have produced novel insights into how SARS-CoV-2 develops resistance to antiviral drugs by investigating the mechanisms of its RNA replication complex.

Specifically, understanding the role of the nsp14 exonuclease and RNA polymerase regulation was expected to lead directly to novel therapeutic strategies effective against current and future coronavirus variants. Termination of funding prematurely ends this crucial research, limiting our ability to develop therapies capable of managing viral resistance.

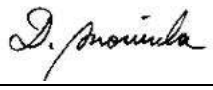
- NIH Project 1P01AI165077-01 (PanCorVac – Center for Pan-Coronavirus Vaccine Development) aimed to develop broadly protective, protein-based vaccines against SARS-CoV-2 variants and other coronaviruses with potential to cause future pandemics. These studies were poised to deliver breakthroughs in vaccine efficacy and durability, significantly enhancing preparedness against a range of coronavirus threats.
- NIH Project 5R01MD018751 (Minority Health and Health Disparities Research Grant) could have resulted in scientific advancements in how to accurately capture the aspects of social support that are most beneficial and protective to individual and community mental health over time. With research-to-date finding that social support is linked to lower risk for all-cause mortality across populations, research from this terminated project could have provided critical information on how to leverage existing individual and community strategies for future intervention development, in turn reducing overall healthcare costs and strain.
- NIH Project P01HD109850 (Child Health and Human Development Extramural Research) could have provided pediatricians and youth-serving professionals with information needed to counsel families about media use and brain development.

Policymakers at the state and federal levels could have benefited from this in contemplating legislation regarding social media, smartphones, and other digital media use being debated across the country.

Conclusion

48. The breakdown in NIH processes is significantly affecting research, institutional operations, and planning. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Executed this 2nd day of April, 2025, in Madison, Wisconsin.



Dorota A. Grejner-Brzezinska, Ph.D.
Vice Chancellor for Research
University of Wisconsin-Madison

WI Decl. of Grejner-Brzezinska, Ex. A - 4.2.2025

Outlook

Grant Termination Notification

From Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date Mon 3/24/2025 2:51 PM
To Nick Novak <nick.novak@wisc.edu>





3/24/2025

Nick Novak
University Of Wisconsin-Madison
nick.novak@wisc.edu

Dear Nick Novak:

Effective with the date of this letter, funding for Project Number 5R01AI158463-04 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 8/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI158463
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
Robert N Kirchdoerfer, PHD
Assistant Professor
rnkirchdoerf@wisc.edu
608-262-6191

8. Authorized Official
Nick Novak
preaward@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Lindsey Ann Freeman

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
lindsey.kisliuk@nih.gov
301.761.6896

10. Program Official Contact Information
Mary Katherine Bradford Plimack

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
kate.plimack@nih.gov
(240) 447-9748

Federal Award Information

11. Award Number
5R01AI158463-04

12. Unique Federal Award Identification Number (FAIN)
R01AI158463

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Coronavirus RNA synthesis by multicomponent protein machines

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08/01/2023 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$389,042
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$389,042
26. Project Period Start Date 08/05/2020 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,738,787

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI158463-04 REVISED

Principal Investigator(s):
Robert N Kirchdoerfer, PHD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI158463. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$92,144
Fringe Benefits	$19,327
Personnel Costs (Subtotal)	$111,471
Materials & Supplies	$40,000
Travel	$6,000
Other	$4,000
Publication Costs	$6,000
Equipment or Facility Rental/User Fees	$75,000
Tuition Remission	$12,000
Federal Direct Costs	$254,471
Federal F&A Costs	$134,571
Approved Budget	$389,042
Total Amount of Federal Funds Authorized (Federal Share)	$389,042
TOTAL FEDERAL AWARD AMOUNT	$389,042
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$389,042	$389,042

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: RAI158463ACV
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
AI	8056323	$389,042

NIH Administrative Data:
PCC: M51C B / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:04:46 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI158463-04 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI158463-04 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor

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should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI158463. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI158463-04 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revised Award: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention

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Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes previous Notice of Award dated **06/26/2024**. All other terms and conditions still apply to this award.

****

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the 04 year as agreed to in the correspondence dated **05/16/2024**. This is the only mid-project extension that will be allowed for the remainder of the project period.

This award also removes the no-cost extension authority of the NIH Standard Terms and Conditions of Award. NIAID prior approval is required to extend the project period end date for this award.

Supersedes previous Notice of Award dated **05/25/2023**. All other terms and conditions still apply to this award.

****

This award provides funds of $389,042 Total Costs ($254,471 Direct Costs and $134,571 F&A Costs) to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds provide support for the period 8/1/2023-7/31/2024. These funds are restricted to prevent, prepare for, and respond to coronavirus domestically or internationally only as described in the application submitted on 6/9/2020 and subsequent documentation submitted 5/10/2023, and may not be rebudgeted or used for any other purpose without NIAID prior approval.

***

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

***

Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.

If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI158463-04 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 4
Salaries and Wages	$92,144
Fringe Benefits	$19,327
Personnel Costs (Subtotal)	$111,471
Materials & Supplies	$40,000
Travel	$6,000
Other	$4,000
Publication Costs	$6,000
Equipment or Facility Rental/User Fees	$75,000
Tuition Remission	$12,000
TOTAL FEDERAL DC	$254,471
TOTAL FEDERAL F&A	$134,571
TOTAL COST	$389,042

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$242,471
F&A Costs 1	$134,571

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WI Decl. of Grejner-Brzezinska, Ex. B - 4.2.2025

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# P01AI165077
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
YOSHIHIRO KAWAOKA, DVM
Professor
yoshihiro.kawaoka@wisc.edu
608-265-4925

8. Authorized Official
Brenda Egan
nih@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Elizabeth R. Sihombing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
elizabeth.sihombing@nih.gov
240-669-5530

10. Program Official Contact Information
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
1P01AI165077-01

12. Unique Federal Award Identification Number (FAIN)
P01AI165077

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
PanCorVac (Center for Pan-Coronavirus Vaccine Development)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/16/2021 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$7,000,324
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$7,000,324
26. Project Period Start Date 09/16/2021 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,000,324

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1P01AI165077-01 REVISED

Principal Investigator(s):
YOSHIHIRO KAWAOKA, DVM

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number P01AI165077. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
Federal Direct Costs	$6,170,370
Federal F&A Costs	$829,954
Approved Budget	$7,000,324
Total Amount of Federal Funds Authorized (Federal Share)	$7,000,324
TOTAL FEDERAL AWARD AMOUNT	$7,000,324
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$7,000,324	$7,000,324

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: PAI165077AC6
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
AI	8050485	$7,000,324

NIH Administrative Data:
PCC: M51Q S / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:01:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01AI165077-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P01AI165077-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

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awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01AI165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1P01AI165077-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

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Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes previous Notice of Award dated **08/30/2024**. All other terms and conditions still apply to this award.

*****

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the letter dated **07/30/2024**. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

This is the final extension that will be allowed for this project.

Supersedes previous Notice of Award dated **05/26/2023**. All other terms and conditions still apply to this award.

*****

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

REVISED AWARD: This award is revised to remove the requirement to submit an extension application for years four and five of the project period.

This Notice of Award removes carryover authority on this award.

Supersedes previous Notice of Award dated 09/17/2021. All other terms and conditions still apply to this award.

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

The budget period anniversary start date for future year(s) will be **September 1.**

This Notice of Award (NoA) includes funds for activity with **Georgia Tech Research Corporation** in the amount of **$1,404,775** (**$887,974** direct costs + **$516,801** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Chicago** in the amount of **$984,000** (**$600,000** direct costs + **$384,000** F&A costs).

This Notice of Award (NoA) includes funds for activity with **St. Jude Children's Research Hospital** in the amount of **$1,364,994** (**$749,997** direct costs + **$614,997** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$972,246** (**$573,597** direct costs + **$398,649** F&A costs).

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In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan
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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the **Just-In-Time**. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

BEN-GURION UNIVERSITY OF THE NEGEV, ISRAEL

Duke-NUS Medical School, SINGAPORE

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used. When submitting future Progress Reports indicate at the beginning of the report:

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If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01AI165077-01 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1
Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
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Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
TOTAL FEDERAL DC	$6,170,370
TOTAL FEDERAL F&A	$829,954
TOTAL COST	$7,000,324

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$540,971
F&A Costs 1	$300,239
F&A Cost Rate 2	55.5%
F&A Cost Base 2	$471,971
F&A Costs 2	$261,944
F&A Cost Rate 3	55.5%
F&A Cost Base 3	$482,471
F&A Costs 3	$267,771

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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WI Decl. of Grejner-Brzezinska, Ex. C - 4.2.2025



03/20/2025

Darlene Holte
UNIVERSITY OF WISCONSIN-MADISON
NIH@rsp.wisc.edu

Dear Darlene Holte:

Effective with the date of this letter, funding for Project Number 5R01MD018571-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 03/01/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 12:18:35 -04'00'

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# R01MD018571
Federal Award Date
03/20/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
Elliot Tebbe, PHD (Contact)

tebbe@wisc.edu
320-339-9992

8. Authorized Official
Darlene Holte

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
Crystal Barksdale
Health Scientist Administrator/program Official
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
crystal.barksdale@nih.gov
301-402-1366

Federal Award Information

11. Award Number
5R01MD018571-02

12. Unique Federal Award Identification Number (FAIN)
R01MD018571

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A multidimensional investigation of social support for transgender and nonbinary people and its impacts on health and well-being: Measurement development using community engagement

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2025 **– End Date** 03/20/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$681,042
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$681,042
26. Project Period Start Date 08/19/2024 **– End Date** 03/20/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,454,524

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5R01MD018571-02 REVISED

Principal Investigator(s):
Stephanie L Budge, PHD
Elliot Tebbe (contact), PHD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD018571. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$236,198
Fringe Benefits	$82,392
Personnel Costs (Subtotal)	$318,590
Consultant Services	$4,499
Materials & Supplies	$8,635
Travel	$7,290
Other	$81,383
Subawards/Consortium/Contractual Costs	$23,986
ADP/Computer Services	$180
Federal Direct Costs	$444,563
Federal F&A Costs	$236,479
Approved Budget	$681,042
Total Amount of Federal Funds Authorized (Federal Share)	$681,042
TOTAL FEDERAL AWARD AMOUNT	$681,042
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$681,042	$681,042

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	RMD018571A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
MD	8472687	$681,042

NIH Administrative Data:
PCC: CPS11 / **OC**: 41025 / **Released**: 03/20/2025
Award Processed: 03/21/2025 12:20:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MD018571-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01MD018571-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

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awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MD018571. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 5R01MD018571-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

INFORMATION: This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Therefore, this project is terminated. The

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University of Wisconsin-Madison may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 2/18/2025 ALSO APPLY TO THIS AWARD:

INFORMATION: This non-competing award has been made at 90% of the level committed for FY2025. If the final appropriation permits, adjustments may be made up to the FY2025 funding plan level.

RESTRICTION: This program must not promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics.

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/2020, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address:
https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address:
http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: The awardee is required to follow the Data Management and Sharing Plan included in the competing application and may not implement any changes in the plan without the written prior approval of the National Institute on Minority Health and Health Disparities.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension

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and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD018571-02 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 2
Salaries and Wages	$236,198
Fringe Benefits	$82,392
Personnel Costs (Subtotal)	$318,590
Consultant Services	$4,499
Materials & Supplies	$8,635
Travel	$7,290
Other	$81,383
Subawards/Consortium/Contractual Costs	$23,986
ADP/Computer Services	$180
TOTAL FEDERAL DC	$444,563
TOTAL FEDERAL F&A	$236,479
TOTAL COST	$681,042

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$426,088
F&A Costs 1	$236,479

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WI Decl. of Grejner-Brzezinska, Ex. D - 4.2.2025

Bulls, Michelle G. (NIH/OD) [E]
Christy Schulz
Grant Termination Notification
Friday, March 21, 2025 12:19:34 PM
image002.png



3/21/2025

Schulz, Christy R
University Of Wisconsin-Madison
crschulz@wisc.edu

Dear Schulz, Christy R:

Effective with the date of this letter, funding for Project Number 5P01HD109850-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10]

See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN
Branch Chief
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov
(301) 435-2307

Federal Award Information

11. Award Number
5P01HD109850-03

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,484,126
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,484,126
26. Project Period Start Date 09/12/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$4,567,357

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P01HD109850-03 REVISED

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
Federal Direct Costs	$995,547
Federal F&A Costs	$488,579
Approved Budget	$1,484,126
Total Amount of Federal Funds Authorized (Federal Share)	$1,484,126
TOTAL FEDERAL AWARD AMOUNT	$1,484,126
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,484,126	$1,484,126

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: PHD109850A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$1,484,126

NIH Administrative Data:
PCC: CDBB -CG / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:09:05 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P01HD109850-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5P01HD109850-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5P01HD109850-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, it is the policy of NIH not to prioritize such research programs.

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CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your

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position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

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NICHD 1% Reduction
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Notice of Funding Opportunity
This award is subject to the requirements indicated in **RFA-HD-22-009**, which are hereby incorporated by reference. See the NIH Funding site for more information.

Non-SNAP Type 5
NIH staff has determined that the submitted Research Performance Progress Report is within the approved scope of work.

Human Subjects
For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Subproject
Subproject funding information is available via the NIH RePORTER System.

SPREADSHEET SUMMARY
AWARD NUMBER: 5P01HD109850-03 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 3
Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
TOTAL FEDERAL DC	$995,547

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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EXHIBIT 30

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF MEGAN A. MORENO

I, Megan A. Moreno, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Department of Pediatrics Vice Chair of Academic Affairs in the University of Wisconsin–Madison (UW–Madison) School of Medicine and Public Health. I am a tenured Professor in the Department of Pediatrics. I am familiar with the facts and information in the statements set forth below, either through personal knowledge or in consultation with UW–Madison faculty.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I have been a Professor and Division Chief in the UW–Madison Department of Pediatrics since 2017 and have served as the Vice Chair of Academic Affairs for the Department since 2020. I am the co-medical director of the American Academy of Pediatrics (AAP) Center of Excellence: Creating a Healthy Digital Ecosystem for Children and Youth. I have served as a

reviewer for more than thirty academic journals in the fields of pediatrics, adolescent health, medical education, digital health, behavioral health, and public health; I currently serve as associate editor of *JAMA Pediatrics* and am an editorial board member for the *Journal of Adolescent Health*. I received my medical degree from George Washington University, a master of educational psychology degree from UW–Madison and a master of public health degree from the University of Washington. I have written a parenting handbook focused on healthy media use, as well as edited several textbooks on media and adolescent health. I have been honored to receive the AAP Council of Communications and Media's Holroyd-Sherry Award for Career Achievement (2020), an American Pediatrics Society Norman J. Siegel New Member Outstanding Science Award (2021–2022), and a Wisconsin Alumni Research Foundation Kellett Mid-Career Fellowship at UW–Madison (2021).

4. My research focuses on the intersection of technology and adolescent health. I am the principal investigator of the UW–Madison Social Media and Adolescent Health Research Team (SMAHRT). At SMAHRT, our research focuses on adolescent technology use and misuse, online safety, and social media influence on health behaviors. The National Institutes of Health ("NIH"), within the U.S. Department of Health and Human Services ("HHS") has been a key funder of SMAHRT's research going back more than fifteen years. I have had continuous federal funding as a principal investigator since the start of my faculty career, including funding from four NIH institutes (National Institute of Child Health and Human Development ["NICHD"], National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, and National Cancer Institute) and the U.S. Department of Justice. I served on the NIH Health, Behavior, and Context (CHHD-M) study section for six years. I am in the process of being onboarded to the NIH's National Advisory Child Health and Human Development (NACHHD)

Council and attended the January 2025 meeting. I have four pending NIH grant applications related to adolescent health, digital media and promoting healthy behaviors and, as further described below, one active (but purportedly terminated) NIH grant supporting SMAHRT and other research on campus investigating how technology and social media content relate to adolescent mental and behavioral health and wellbeing.

5. I am providing this declaration to detail my experience in applying for and reviewing NIH grant applications.

6. I am also providing this declaration to explain the impacts of grant terminations and delays in grant application review upon my staff, my research, and the people who benefit from it.

7. The terminations and delayed review of grant applications severely impacts me, SMAHRT, and other campus researchers and trainees. Full termination of my current NIH grant would have devastating impacts on our research teams, leading to profound layoffs among staff and trainees, including students. Moreover, it would squander taxpayer dollars invested in the projects thus far, and prevent pediatricians and youth-serving professionals from having the information they need to counsel families about media use and brain development. Additionally, delays in the review of my currently pending grant applications create uncertainty and disrupt the funding cycle necessary to maintain continuity of research projects and consistent staffing of trained researchers.

Reliance on NIH Funding

8. My current NIH award is a Research Program Grant (known as a P01), funded through a one-time Funding Opportunity Announcement titled, “Impact of Technology and Digital Media (TDM) Exposure/Usage on Child and Adolescent Development.” NIH P01s fund

broad, multidisciplinary, longitudinal research programs involving groups of investigators, each working on individual research projects supported by one or more research cores that contribute to the overall program objectives. My particular award supports two additional co-investigators on three independent projects with support from two campus research cores: Dr. Ellen Selkie, MD, MPH, Assistant Professor and Fellowship Program Director in the UW–Madison Department of Pediatrics; and Dr. Christopher Cascio, PhD, Associate Professor in the UW–Madison School of Journalism and Mass Communication.

9. This funding opportunity was highly competitive and intended to fund one award focused on adolescent health and media, and one focused on media use in young children. P01 funding opportunities are rare, and this particular call for applications was the first media-focused P01 at the NIH. We were awarded the P01 focused on adolescent health in this prestigious and first-of-its-kind funding opportunity. The program grant is titled, "A longitudinal study investigating TDM [technology and digital media] and adolescent health and development: Behavior, Neuroscience and Socioemotional Well-being." Our research program is the largest endeavor of its kind, having recruited over three hundred youth so far from across Wisconsin, with the goal of recruiting four hundred. The three projects encompassed by this grant all address a major health issue for Americans: the impact of media on adolescent physical and mental health, health behaviors, and brain development.

10. The P01 award provides salary support for the three faculty co-investigators (myself, 30%; Dr. Selkie, 40%; and Dr. Cascio, 42%). This significant salary support from the NIH creates protected time for each of us to not only conduct the research, but support undergraduate, graduate and post-doctoral trainees. All three investigators dedicate significant time to engage in mentoring and teaching of the trainees involved in the projects that comprise

this program. Further, Dr. Selkie is an assistant professor and early career faculty. She has received research training sponsored by NICHD funding through a K23 career development award, and participated in the NIH's Loan Repayment Program. Thanks to NIH's ongoing support of Dr. Selkie's career development she is able to lead one of the three projects that make up this P01.

11. Forty students — including undergraduate, graduate, and medical students — participate in the projects under this research program. They rely on NIH awards for Research and Project Assistant positions and summer support as they progress toward their degree. Loss of funding would disrupt graduate student data collection and support of secondary aims that were developed for dissertation research. This also impacts undergraduate educational opportunities in health research, potentially reducing the future STEM workforce in the U.S. The P01 also supports ten university staff who face reduced hours or layoffs without the funding. Finally, this P01 program grant involves several co-investigators from outside institutions, including from Texas, Ohio, Michigan and Pennsylvania, who will all lose the salary support and collaboration opportunities provided by this P01 grant if it is terminated.

Typical Timeline and Processes for NIH Grant Awards

12. For NIH grants, the first step in the process is typically a Notice of Funding Opportunity ("NOFO"), which may be a broad call for investigator-initiated proposals, or a more specific notice related to topics of emphasis. Some of these establish specific due dates, but for most there are standard deadlines based on the type of grant at issue. The standard due dates align with three annual review and funding cycles. For example, for research grants, the standard due dates fall in February, June, and October.

13. Grant applications are typically submitted via NIH's online portal, which also allows the applicant to track the status of the grant, and provides access to scores and summaries generated by study sections and advisory councils.

14. Study sections and advisory council meetings are typically scheduled to align with these three funding cycles, with numerous study sections held in each cycle prior to advisory council meetings.

15. In my previous experience as a reviewer on a study section, I was typically assigned 6-10 grants to review. This is an intensive and rigorous process, which typically takes 2-3 hours of my time for each grant in advance of the study section meeting. To be able to effectively present and discuss each of my assigned grants at the study section meeting, I typically need to conduct my review shortly before the meeting occurs. After reviewing the grant at the study section, we provide each with a score. This score, along with a summary statement that summarizes the discussion, is provided to the applicant and to the advisory council, which convenes to finalize funding decisions. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-to-5 year terms, though some may be longer and others may be shorter.

16. Although the life of the grant is often longer, funding is provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the stated project goals, in my experience such renewals are typically granted.

17. These regular cycles and predictable renewals are essential for the continuity of funding for my research team. In order to maintain staffing, I plan ahead for future grant submissions years in advance to ensure the end of one grant cycle is aligned with obtaining new grants. This reliable process is essential to maintaining a trained workforce within a research group and ensuring levels of staffing remain consistent and efficient. Further, the pursuit of new grants also allows our team to continue a line of research to its conclusion, as one project will answer a critical question that then leads to a next critical question. For example, if a project shows that a particular health intervention is effective and could be used in clinical settings, a subsequent project is needed to determine how to effectively scale and disseminate that new intervention.

18. In my experience, termination of an active grant is extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Delays and Irregularities in the Processing of NIH Grant Applications

19. Since late January 2025, I have seen an unusual number of delays in processing my grant applications, as well as in the grant review process in which I participate as a reviewer.

20. For example, in the past year I submitted four new grant applications, all of which remain pending. One grant was submitted in fall and scheduled for review in February 2025; however, this grant review was abruptly cancelled the week of the study section. In prior years, I would have expected to receive a score and summary statement on my applications by February 2025, and to have the advisory committee meeting for the current cycle occur in June. Based on scores or outcomes, this would have left me with time to prepare new applications, or address

issued raised and resubmit this application for funding this year. However, this year, the study section review was inexplicably delayed, and only this past week was rescheduled for late April. I have not received any formal communication explaining the delay.

21. In the past, I have consistently received timely scores and communications from NIH regarding my applications.

22. In my role as a division chief and vice chair in the Department of Pediatrics, I provide mentoring and supervision of faculty who also serve on study sections. Through this work, I have learned that at a March 2025 study section, reviewers were directed to "refrain from evaluating, scoring, or incorporating diversity, equity, and inclusion into the final scoring. Additionally, kindly avoid mentioning these terms in your critiques." During the study section meeting, multiple section members were interrupted when speaking and told by NIH staff to refrain from use of these terms. Two weeks before the study section, two grants were suddenly removed from review "while NIH undertakes a review of its research priorities under NIH's statutory and regulatory authorities." NIH staff have told faculty in our department that future grants related to gender identity will not be accepted. These new approaches do not align with the priorities of child health, scientific merit, and processes that have served the NIH since its inception.

23. As an incoming member of the NAACHD council, I completed the onboarding process, which included extensive background checks, orientation meetings, and taking the Oath of Office. I learned that in this role, I would receive a list of grants with scores and summary statements generated by numerous study sections reviewing grants for NICHD. These are ranked by the advisory council, and a list of grants recommended for funding is generated. I attended an initial meeting and observed these highly rigorous, transparent processes in action. However, in

early February I was informed that they were unable to complete the certification for any new Advisory Council members, and that I and other new members would remain in a holding pattern. This delay, uncertainty, and wasted time in the onboarding process for all involved is unprecedented, inefficient, and has no benefits.

Irregularities in Grant Terminations

24. We recently received a letter from NIH purporting to terminate the P01 grant referenced in paragraph 8 above because it does not "effectuate agency priorities."

25. NIH initially issued our award on September 12, 2022, with an anticipated total budget of $7.57 million (~$1.5 million per year) for a term of five years. Initial Notice of Award (Sept. 12, 2022), attached hereto as Exhibit A. As of the date the grant was terminated, UW–Madison had drawn $3.51 million, with an anticipated additional disbursement of $4.06 million over the next 2.5 years.

26. On March 21, 2025 the university received a Grant Termination Notification via email from Michelle Bulls, Director of the NIH Office of Policy for Extramural Research Administration. Email from Michelle G. Bulls to Christy Schulz (Mar. 21, 2025), attached hereto as Exhibit B. This was followed by a new Notice of Award (NOA), dated March 25, 2025, confirming termination and directing the university on closeout procedures. Terminating Notice of Award (Mar. 25, 2025), attached hereto as Exhibit C. Both the email and the NOA provided only the following explanation for why the award no longer "effectuates agency priorities": "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." Beyond this assertion, NIH did not include any explanation on what

those new agency priorities are, or why our research program specifically no longer furthers those priorities. I was not referred to any new policy statement or regulation that described the new agency priorities, and efforts to obtain further clarification from NIH were unsuccessful, seemingly due to staffing reductions and changes at NIH. Our Program Officer's position was terminated in February 2025. The next Program Officer assigned to our program grant retired ten days after the termination email was received, so we were unable to meet with or gain any clarifying information from him. As of the date of this declaration, we do not know who our Program Officer is, and have not received any communication from the new Acting Branch Chief.

27. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that the NICHD's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Specifically, our research program is funded under the Child Health and Human Development Extramural Research Assistance Listing Program, which – as of the date of this declaration – was last updated on February 27, 2025. SAM.gov Assistance Listing Directory Search Results (Apr. 1, 2025), attached hereto as Exhibit D. The Assistance Listing description of fiscal year 2025 funding projects indicates that, "[r]esearch on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth." SAM.gov Child Health and Human Development Extramural Research Assistance Listing (Apr. 1, 2025), attached hereto as Exhibit E. Additionally, in a March 20, 2025 interview, HHS Secretary Robert F. Kennedy, Jr. stated that, among children, "social media use on cellphones has been directly

connected with depression, with poor performance in schools, with suicidal ideation, with substance abuse," highlighting it as a particular area of concern for the Department. Fox and Friends, *RFK Jr. launches investigation into 'high levels' of heavy metals in baby formula* (Mar. 20, 2025, 8:48 AM) https://www.foxnews.com/video/6370269070112.

28. Our research program advances the above goals in several ways. This project focuses on the impact of media on brain development, health behaviors, and media's influence on healthy and risky behaviors, and how media impacts socioemotional development. The data, if collected, would give us the unique opportunity to examine the effects of digital and social media use over time, in contrast to studies that only include a single time point, and which have failed to answer important questions about the relationship between social media use and change in health outcomes. We would determine, through longitudinal data, the impact of social media use on the developing brain of adolescents. We would also understand how adolescents share information about health and risk behaviors (such as physical activity, sleep, and alcohol use) on social media, and are influenced by content about those behaviors. Finally, we would leverage our data to provide information and resources to teens and families about specific social media behaviors and actions that may enhance well-being and mental health. Families across the country are aware of and concerned about media's impact on mental health, as well as physical health, including obesity and sleep. Pediatricians struggle to provide accurate information to parents because the impact of media on children's development, including brain development and impact on behavior, is not known. All three projects in this program grant are designed to fill this gap in understanding. A critical part of this work is to give back to the local communities across Wisconsin and to provide new insight into the impacts of digital and social media on

youth and families. These insights are also critical for healthcare providers, educators, policymakers, and community members, and a range of other stakeholders

29. The March 21, 2025 Notice of Termination email also stated the following: "Although 'NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,' no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Exhibit B, quoting NIH Grants Policy Statement at IIA-156. To the extent NIH is asserting that corrective action is impossible because the premise of the entire research program is "based on gender identity," NIH provides no information supporting that assertion, and it is incorrect. Of the three projects under this award, one aim of one project includes a comparison of sexual and gender minority youth and non-sexual gender minority youth with respect to social media engagement to understand different strategies and impacts of technology and digital media on wellbeing between these groups. However, at no point was the university contacted by the Program Official, Grants Management Officer, or any other representative of NIH to share NIH's concern about the scope of the research program or discuss possible modifications. With so much time, funding, and other resources already invested in the program, terminating now without apparently even considering modification feels particularly wasteful.

Comparisons Across Administrations

30. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses and awards. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

31. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my and other UW–Madison faculty communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

32. Due to the termination, delays and funding uncertainty, my lab will be forced to: suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts; terminate employment of research staff, who will be forced to seek other employment; and stop ongoing data collection in this longitudinal study, compromising time-sensitive components of the research. Interruption of data collection in a longitudinal study puts all of the work of the research team and the participants to waste if the full study data is not completed.

33. If this grant is terminated, the three faculty co-investigators will no longer have the salary support that creates protected time for research and student mentoring. Undergraduate students working on projects funded by this P01 rely on the research program to obtain required experience to pursue master's degrees, PhDs, and MDs. These students are likely to change career course if they cannot build the necessary experiences to gain admission to post-graduate programs. Graduate students and post-doctoral trainees who rely on research conducted within our P01 to obtain their PhDs are likely to see years of delay in their progression and career development as a result of termination.

34. With termination of NIH funding, Dr. Selkie's research and faculty career will be significantly and negatively impacted, including risks to her overall research program and faculty trajectory. Prior NIH-funded training for her scientific career (as detailed above) will have been squandered.

35. Finally, this P01 termination also impacts the families who have committed to being part of this project. Parents have driven their adolescents across the state for MRI appointments, and youth have shared information about their social media use with us over months and years. This termination would put all of the work of those participants and their families to waste. It would also squander the taxpayer dollars that had supported it thus far because halting the study during the longitudinal data collection dashes our chances of observing the temporal relationships between social media use and outcomes that so many other studies were not designed to address. This termination would also prevent pediatricians and youth-serving professionals from having the information they need to counsel families about media use and brain development. Policymakers at the state and federal levels would also benefit from this data as they contemplate legislation regarding social media, smartphones, and other digital media use being debated across the country.

36. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

37. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure

talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

Executed this 2nd day of April, 2025, in Madison, Wisconsin.

/s/ Megan A. Moreno
Megan A. Moreno
Professor, Vice Chair of Academic Affairs
Department of Pediatrics
University of Wisconsin–Madison

WI Decl. of Moreno, Ex. A
4.2.2025

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
09-12-2022

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301

MADISON, 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov

Federal Award Information

11. Award Number
1P01HD109850-01

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-12-2022 **– End Date** 08-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$1,580,159
20 a. Direct Cost Amount	$1,025,587
20 b. Indirect Cost Amount	$554,572
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,580,159
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,580,159
26. Project Period Start Date 09-12-2022 **– End Date** 08-31-2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,580,159

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Sarah M Lee

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(301) 435-2307

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1P01HD109850-01

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,580,159 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Sarah M Lee
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$548,938
Fringe Benefits	$186,212
Personnel Costs (Subtotal)	$735,150
Consultant Services	$21,000
Materials & Supplies	$14,000
Travel	$18,000
Other	$109,050
Subawards/Consortium/Contractual Costs	$98,387
Publication Costs	$10,000
ADP/Computer Services	$2,000
Tuition Remission	$18,000

Federal Direct Costs	$1,025,587
Federal F&A Costs	$554,572
Approved Budget	$1,580,159
Total Amount of Federal Funds Authorized (Federal Share)	$1,580,159
TOTAL FEDERAL AWARD AMOUNT	$1,580,159
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,580,159

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$1,580,159	$1,580,159
2	$1,503,072	$1,503,072
3	$1,499,116	$1,499,116
4	$1,491,340	$1,491,340
5	$1,497,560	$1,497,560

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PHD109850A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025	2026
HD	8014702	$1,580,159	$1,503,072	$1,499,116	$1,491,340	$1,497,560

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -JG / **OC**: 41021 / **Released**: Lee, Sarah 09-01-2022
Award Processed: 09/12/2022 12:07:16 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01HD109850-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

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SECTION III – STANDARD TERMS AND CONDITIONS – 1P01HD109850-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

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In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1P01HD109850-01

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to NICHD notification to the recipient that the identified issues have been resolved and this restriction is removed.

The verification of IRB approval must be submitted no later than **November 30, 2022**, to the Grants Management Specialist indicated on this Notice of Award. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

Delayed Start Date

This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **September 1.**

Escalation

In accordance with the NICHD FY2022 fiscal policy, escalation on recurring costs has been removed.

Salary CAP

No award funds shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See NIH Guide Notice NOT-OD-22-076.

Subproject

Subproject funding information is available via the NIH RePORTER System.

Overlap

This award is contingent upon the adjustment in Dr. Ellen M. Selkie's effort as described in the updated Other Support/JIT dated 08/01/2022.

Human Subjects

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 “NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research”. All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical

trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

COVID-19

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. Please contact the Grants Management Specialist and Program Official indicated on this Notice of Award for more information.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01HD109850-01

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$548,938	$548,938	$559,818	$559,817	$559,817
Fringe Benefits	$186,212	$186,212	$190,347	$190,347	$190,347
Personnel Costs (Subtotal)	$735,150	$735,150	$750,165	$750,164	$750,164
Consultant Services	$21,000	$21,000	$13,000	$13,000	$13,000
Materials & Supplies	$14,000	$14,000	$6,000	$6,000	$6,000
Travel	$18,000	$18,000	$18,000	$18,000	$18,000
Other	$109,050	$88,050	$90,050	$85,050	$89,050
Subawards/Consortium/Contractual Costs	$98,387	$98,387	$98,387	$98,387	$98,387
Publication Costs	$10,000	$10,000	$10,000	$10,000	$10,000
ADP/Computer Services	$2,000	$2,000	$2,000	$2,000	$2,000
Tuition Remission	$18,000	$18,000	$18,000	$18,000	$18,000
TOTAL FEDERAL DC	$1,025,587	$1,004,587	$1,005,602	$1,000,601	$1,004,601
TOTAL FEDERAL F&A	$554,572	$498,485	$493,514	$490,739	$492,959
TOTAL COST	$1,580,159	$1,503,072	$1,499,116	$1,491,340	$1,497,560

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	55.5%	55.5%	55.5%	55.5%	55.5%
F&A Cost Base 1	$999,228	$898,172	$889,215	$884,214	$888,214
F&A Costs 1	$554,572	$498,485	$493,514	$490,739	$492,959

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WI Decl. of Moreno, Ex. B
4.2.2025

From: Bulls, Michelle G. (NIH/OD) [E]
To: Christy Schulz
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:19:34 PM
Attachments: image002.png



3/21/2025

Schulz, Christy R
University Of Wisconsin-Madison
crschulz@wisc.edu

Dear Schulz, Christy R:

Effective with the date of this letter, funding for Project Number 5P01HD109850-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10]

See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

WI Decl. of Moreno, Ex. C
4.2.2025

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN
Branch Chief
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov
(301) 435-2307

Federal Award Information

11. Award Number
5P01HD109850-03

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,484,126
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,484,126
26. Project Period Start Date 09/12/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$4,567,357

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P01HD109850-03 REVISED

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
Federal Direct Costs	$995,547
Federal F&A Costs	$488,579
Approved Budget	$1,484,126
Total Amount of Federal Funds Authorized (Federal Share)	$1,484,126
TOTAL FEDERAL AWARD AMOUNT	$1,484,126
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,484,126	$1,484,126

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PHD109850A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
HD	8014702	$1,484,126

NIH Administrative Data:
PCC: CDBB -CG / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:09:05 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P01HD109850-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5P01HD109850-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5P01HD109850-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, it is the policy of NIH not to prioritize such research programs.

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CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your

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position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

NICHD 1% Reduction
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Notice of Funding Opportunity
This award is subject to the requirements indicated in **RFA-HD-22-009**, which are hereby incorporated by reference. See the NIH Funding site for more information.

Non-SNAP Type 5
NIH staff has determined that the submitted Research Performance Progress Report is within the approved scope of work.

Human Subjects
For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Subproject
Subproject funding information is available via the NIH RePORTER System.

SPREADSHEET SUMMARY
AWARD NUMBER: 5P01HD109850-03 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 3
Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
TOTAL FEDERAL DC	$995,547

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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- ◉ All Words
- ○ Exact Phrase

e.g. 64.106

93.865 ×

Dates

Federal Organizations

Eligibility

Assistance Type

Location

Status

- [x] Active
- [ ] Inactive

Reset

Federal Assistance | **Assistance Listings** | **Subaward Reports**

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Last Updated Date: New - Old

Showing 1 - 5 of 5 results

93.865 Child Health and Human Development Extramural Research

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human dev...

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Feb 27, 2025

Type of Assistance
B-Cooperative Agreements (Discretionary Grants), B-Project Grants

93.361 Nursing Research

Nurses understand that improving health and well-being means addressing people's needs in multiple settings, contexts, and over the whole life course....

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Nov 18, 2024

Type of Assistance
B-Cooperative Agreements, M-Training, B-Project Grants

93.977 Sexually Transmitted Diseases (STD) Prevention and Control Grants

The purpose of the assistance is to strengthen STD prevention programs in eligible jurisdictions. Project grants awarded under Section 318 to State an...

Assistance Listing

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

93.978 Sexually Transmitted Diseases (STD) Provider Education Grants

Assistance Listing

The purpose of the assistance is to fund academic institutions and clinical and public health training organizations to develop, deliver and evaluate ...

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

93.286 Discovery and Applied Research for Technological Innovations to Improve Human Health

Assistance Listing

To support hypothesis-, design-, technology-, or device-driven research related to the discovery, design, development, validation, and application of ...

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

Last Updated Date
Nov 11, 2024

Type of Assistance
B-Cooperative Agreements (Discretionary Grants), B-Project Grants (Discretionary)

+ History

page 1 of **1** *results per page* 25

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ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing
Overview
Authorizations
Financial Information
Criteria for Applying
Applying for Assistance
Compliance Requirements
Contact Information
History

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

View available opportunities on Grants.gov related to this Assistance Listing

Overview

Objectives

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

Examples of Funded Projects

Fiscal Year 2024: The NICHD program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. Most U.S. women will be affected by one or more gynecological disorders during their lifetime. NICHD manages a broad research portfolio to better understand, treat, and prevent these common, painful, and costly conditions, including endometriosis, uterine fibroids, Polycystic Ovary Syndrome, chronic pelvic pain, and pelvic floor disorders. Uterine fibroids are the most common non-cancerous tumors in women and can cause pain and abnormal bleeding. Sometimes fibroids can make it difficult for a woman to become pregnant or maintain a pregnancy. NICHD-supported scientists are working to develop new prevention and treatment approaches. For example, researchers found that a treatment featuring the drug relugolix could help reduce heavy menstrual bleeding and pain associated with fibroids, without loss in bone mineral density. Another research team is looking at a different drug, an anti-inflammatory medication, which reduced the size of fibroid tumors in mice without side effects. Endometriosis is another gynecologic health condition that can cause severe pain, irregular periods, and infertility. Although the condition runs in families, known genes explain less than two percent of cases. To identify more genes that can account for the condition, researchers recently combined the data from two dozen studies that looked at the whole genomes of almost 61,000 women who had endometriosis, as well as another 702,000 who did not. The scientists found 42 locations within the women's DNA that were linked to endometriosis. A closer look revealed genetic connections to 11 pain conditions, such as migraine, headache, back and spinal pain, and multisite chronic pain. Future studies that reveal more about the shared biology between the pain and inflammatory conditions and endometriosis could lead to new therapies. There is an urgent need for safe, effective, and less invasive infertility treatments, as well as contraception options for both men and women. With support from NICHD, male contraceptive agents are already being tested in humans, and even more promising approaches are being developed in animal models. In a mouse study, researchers identified a potential non-hormonal contraceptive compound that could be taken shortly before sexual activity, with fertility restored the very next day. A recently discovered gene expressed only in the reproductive organs is another promising target for male contraception, because deactivating this gene does not appear to interfere with testosterone production and would not block the hormone's other functions, such as regulating sex drive, building bone mass, and muscle strength. As NIH's leader in pregnancy and maternal health research, NICHD supports studies on clinical treatments

to reduce the risk of pregnancy complications for both pregnant women and their offspring. Through NIH's IMPROVE initiative, NICHD established Maternal Health Research Centers of Excellence to develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity across the country. These Centers, comprising 10 research centers, a data innovation and coordinating hub and an implementation science hub. Together, these institutions will work to design and implement research projects to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. They will focus on populations that experience health disparities, including racial and ethnic minorities, socioeconomically disadvantaged populations, those living in underserved rural areas, sexual and gender minority populations and people with disabilities. The IMPROVE initiative also includes two Challenge prize competition initiatives, in addition to traditional grant funding, that provide innovative approaches to well defined barriers in maternal health care and research engagement. The Rapid Acceleration of Diagnostics (RADx® Tech) for Maternal Health Challenge leverages an innovation funnel approach to accelerate the development of maternal health diagnostic or other remote-sensing technologies (e.g., wearable devices, smartphone-enabled tools) to improve access to care in the postpartum period and complement the use of telehealth in areas without sufficient maternity care. The Connecting the Community for Maternal Health Challenge aims to address the structural barriers faced by community and advocacy organizations to conduct maternal health research by helping them build effective research infrastructure and capacity.

Fiscal Year 2025: NICHD continues to improve understanding of the effects of COVID-19 infection and disease during pregnancy, in the postpartum, during lactation, and in newborns, as well as its long term impact, and continues to work toward inclusion of pregnant and lactating people in SARS-CoV-2 vaccine research. A recent study found that by late 2022, widespread COVID-19 vaccination of pregnant people likely halted a spike in the preterm birth rate that began at the start of the pandemic. Another study found that preterm infants receive similar levels of maternal antibody protection as term infants after maternal COVID-19 vaccination. NICHD's research networks play a leading role in clinical research advances for maternal and neonatal health. For example, in a large, multi-country clinical trial, researchers showed that a single dose of the antibiotic azithromycin can reduce the risk of postpartum sepsis and death by one third among women who deliver vaginally. For vulnerable infants, scientists found that extremely preterm infants who were fed fortified human milk grew longer and more rapidly and had larger head circumferences compared with extremely preterm infants fed unfortified human milk. The findings provide support for future studies on the potential benefits of human milk fortification in preventing malnutrition among infants born at 28 weeks or younger. NICHD is represented on the executive and steering committees of the NIH-wide Climate Change and Health Initiative aiming to reduce the health threats posed by climate change across the lifespan. The health effects of climate and environmental changes can affect many stages of a women's reproductive life,

impacting the health of future generations. Growing evidence suggests that heat stress negatively influences fetal growth and pregnancy outcomes, as two recent studies from NICHD's Global Network for Women's and Children's Health illustrate. One study, which evaluated more than 120,000 pregnant women in India and Pakistan, found a higher incidence of pregnancy-related high blood pressure, severe preeclampsia, preterm birth, and low birth weight with greater temperatures. Another study, conducted in Pakistan, found that exposure to excessive heat in early pregnancy was linked to lower infant lengths and head circumferences at birth. The findings also suggest that nutritional supplementation early in pregnancy may help offset some of the effects of heat stress. Research on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth. This research program also supports the evidence base for pediatric medicine, through clinical studies in pharmacology, infectious diseases, endocrinology, trauma and critical illness, and other aspects of health throughout infancy, childhood, and adolescence. Although children have distinct medical needs, and their physiology is not the same as adults, medical practices are often extrapolated from adult research without adequate study specifically in children. The Collaborative Pediatric Critical Care Research Network is funded by NICHD to conduct large-scale, multicenter randomized controlled trials to provide the research needed to make the best medical decisions for children in real-time while they are in the pediatric intensive care unit. Recent research supported through NICHD uncovered links between severe sepsis—a factor in 60 percent of child deaths worldwide—and certain genes related to the child's immune system. These findings are opening the way for genetic screening to tailor sepsis treatment according to a child's specific immune system functioning. NICHD also administers eight grants to refine technologies for early diagnosis of severe illnesses resulting from SARS-CoV-2 infection in children, including Multisystem Inflammatory Syndrome in Children (MIS-C). NICHD-supported researchers recently found that children with COVID-19 who develop MIS-C have unique biochemical indicators of cell injury and cell death, providing a pathway to develop tests that can identify children with MIS-C. Other researchers identified the mechanism by which MIS-C appears to cause shock in children. Inflammation of the blood vessels prevents the vessels from constricting, resulting in low blood pressure and circulation. This finding indicates that medications that constrict the blood vessels may be a preferred treatment option. NICHD supports a broad spectrum of research that seeks to prevent and treat pediatric injuries. To minimize the impact of head injury in youth football, researchers compared the magnitude, frequency, and location of head impacts among youth and college football players to inform the development of age-appropriate guidelines for helmet design and other prevention measures.

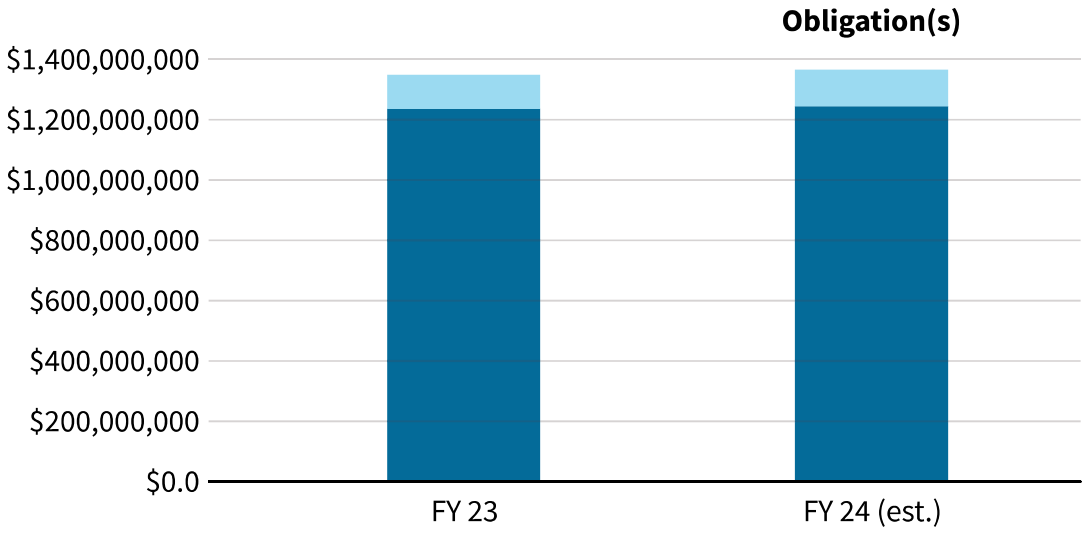
Authorizations

Public Health Service Act, Section 301, 448 and 487, as amended, Public Laws 78-410 and 99-158, as amended, 42 U.S.C. 241; 42 U.S.C. 285g; 42 U.S.C. 288; Small Business

Research and Development Enhancement Act of 1992, Public Law 102-564, Public Law 118-47

Financial Information

These funding amounts do not reflect the award amounts that are displayed on USASpending.gov



Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
☐ **Project Grants Total**	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**
For FY 2023, of the $1,233,369,249 for Total Research Grants, $51,684,492 was for SBIR/STTR activities and awards. For FY 2024, of the $1,241,888,972 for Total Research Grants, $51,395,322 was for SBIR/STTR activities and awards. For FY 2025, of the estimated $1,247,152,000 for Total Research Grants, $51,136,000 is planned for SBIR/STTR activities and awards. NOTE: these amounts	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**

Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
do not include training, R&D contracts of operating funds.			
☐ Cooperative Agreements (Discretionary Grants) Total	**$111,889,797**	**$120,423,704**	**$120,500,000**
Totals	**$1,345,259,046**	**$1,362,312,676**	**$1,367,652,000**

Range and Average of Financial Assistance

For research project grants, fiscal year 2024, range is $50,000 to $5,000,000; average is $534,606. Individual research fellowship awards: Basic stipend (first year beyond the doctoral degree) of approximately $45,000. The sponsoring institution will be provided, on application, with an allowance of up to approximately $8,000 per year to help defray the cost of training. No dependency allowances. SBIR: Average Phase I awards are for approximately $225,000 (grant activity R43 - for up to six months); Phase II awards may be made for amounts up to $1,500,000 (grant activity R44 - for up to two years).

Accomplishments

Fiscal Year 2024: Budget Actuals: Fiscal year 2024 competing and noncompeting research project grants actuals are 1,839. Of this number, 70 were SBIR/ STTR awards. Exactly 61 research centers were awarded. Exactly 423 other research grants were awarded. There were institutional training grants to support 389 trainees that were awarded in fiscal year 2024. The individual training award were 292 for fiscal year 2024.

Fiscal Year 2025: Budget Request: Fiscal year 2025 planned competing and noncompeting research project grants are expected to be 1,859. Of this number, 89 are planned to be SBIR/ STTR awards. An estimated 66 research centers are planned to be awarded. There are plans for 411 other research grants to be awarded. There are plans for institutional training grants to support 409 trainees to be awarded in fiscal year 2025. The individual training awards are estimated at 299 for fiscal year 2025.

Account Identification

75-0844-0-1-552-DHHS/NIH/ Eunice Kennedy Shriver National Institute

Criteria for Applying

Types of Assistance

B - Project Grants, B - Cooperative Agreements (Discretionary Grants)

Credentials and Documentation

Applicants should submit electronically via Grants.gov as directed in the relevant NIH Funding Opportunity Announcement. All required forms specified in the application kit are to be completed by the applicant and submitted with the application package. National Research Service Award: Individual Award: The applicant's academic record, research experience, citizenship, and institution sponsorship should be documented in the application. Institutional Award: the applicant organization must show the objectives, methodology, and resources for the research training program, the qualifications and experience of directing staff, the criteria to be used in selecting individuals for awards, and a detailed budget and justification for the amount of grant funds requested. For-profit organizations' costs are determined in accordance with 48 CFR, Subpart 31.2 of the Federal Acquisition Regulations. For other grantees, costs will be determined by HHS Regulations, 45 CFR, Part 74, Subpart Q. For SBIR and STTR grants, applicant organization (small business concern) must present in a research plan an idea that has potential for commercialization and furnish evidence that scientific competence, experimental methods, facilities, equipment, and funds requested are appropriate to carry out the plan. 2 CFR 200, Subpart E - Cost Principles applies to this program.

Applicant Eligibility

Designations

State (includes District of Columbia, public institutions of higher education and hospitals), Local (includes State-designated lndian Tribes, excludes institutions of higher education and hospitals, Public nonprofit institution/organization (includes institutions of higher education and hospitals), Individual/Family, Private nonprofit institution/organization (includes institutions of higher education and hospitals)

Universities, colleges, medical, dental and nursing schools, schools of public health, laboratories, hospitals, State and local health departments, other public or private institutions, both nonprofit and for-profit, and individuals. National Research Service Award: Support is provided for academic and research training only, in health and

health-related areas that are periodically specified by the National Institutes of Health. Individuals with a professional or scientific degree are eligible (M.D., Ph.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree). Predoctoral research training grants to institutions are also supported. Proposed study must result in biomedical or behavioral research training in a specified shortage area and which may offer opportunity to research health scientists, research clinicians, etc., to broaden their scientific background or to extend their potential for research in health-related areas. Applicants must be citizens of the United States or be admitted to the United States for permanent residency; they also must be nominated and sponsored by a public or private institution having staff and facilities suitable to the proposed research training. Domestic nonprofit organizations may apply for the institutional NRS grant. SBIR: SBIR grants can be awarded only to domestic small businesses (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed, and have no more than 500 employees). Primary employment (more than one- half time) of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In both Phase I and Phase II, the research must be performed in the U.S. or its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council. STTR grants can be awarded only to domestic small business concerns (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed and have no more than 500 employees) which "partner" with a research institution in cooperative research and development. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent by the research institution. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council.

Beneficiary Eligibility

Designations

Individual/Family, Private nonprofit institution/organization, Student/Trainee, Scientist/Researchers, State, U.S. Citizen, Local, Public nonprofit institution/organization

Any nonprofit or for-profit organization, company, or institution engaged in biomedical or biobehavioral research.

Length and Time Phasing of Assistance

Awards are usually made annually with no project period to exceed 5 years in length. National Research Service Awards: From 1 to 3 years. SBIR: Phase I awards are generally for 6 months; Phase II awards normally may not exceed 2 years. STTR Phase I awards are generally for 1 year; Phase II awards normally may not exceed 2 years. Method of awarding/releasing assistance: Each year, submitted progress reports for awarded grants are reviewed, and if satisfactory progress is demonstrated, a Notice of Grant Award is issued.

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

Grantee agrees to administer the grant in accordance with the regulations and policies governing the research grant programs of the Public Health Service as stated in the terms and conditions on the application for the grant. National Research Service Awards: Awarded to individuals for full-time research training in specified behavioral and biomedical shortage areas. Awardees may utilize some of their time in academic and clinical duties if such work is closely related to their research training. Awards may be made to institutions to enable them to make NRS awards to individuals selected by them. Each individual awardee is obligated upon termination of the award to comply with certain service and payback provisions. SBIR Phase I grants (of approximately 6-months' duration) are to establish the technical merit and feasibility of a proposed research effort that may lead to a commercial product or process. Phase II grants are for the continuation of the research initiated in Phase I and which are likely to result in commercial products or processes. STTR Phase I grants (normally of 1- year duration) are to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort that has potential for commercial application. Phase II funding is based on results of research initiated in Phase I and scientific and technical merit and commercial potential on Phase II application.

Applying for Assistance

Deadlines

Contact the headquarters or regional location, as appropriate for application deadlines

Preapplication Coordination

Preapplication coordination is not applicable. Environmental impact information is not required for this program. This program is excluded from coverage under E.O. 12372.

Application Procedures

2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards applies to this program.
National Research Service Award: Prior to formal application, an individual must arrange for acceptance at a sponsoring institution by a sponsor who will supervise the training. Individuals must be sponsored by a domestic or foreign institution. SBIR/STTR: Same as for grants (above). Applications are submitted electronically via Grants.gov following the general guidance provided at: http://grants.nih.gov/grants/forms.htm and the specific instructions for the respective Funding Opportunities Announcement which may be found at: https://grants.nih.gov/funding/index.htm

Criteria for Selecting Proposals

The major elements in evaluating proposals include assessments of the significance of the proposed research; approach; innovation; investigators; and environment. The following criteria will be used in considering the scientific and technical merit of SBIR/STTR Phase I grant applications: (1) The soundness and technical merit of the proposed approach; (2) the qualifications of the proposed principal investigator, supporting staff, and consultants; (3) the technological innovation of the proposed research; (4) the potential of the proposed research for commercial application; (5) the appropriateness of the budget requested; (6) the adequacy and suitability of the facilities and research environment; and (7) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment. Phase II grant applications will be reviewed based upon the following criteria: (1) The degree to which the Phase I objectives were met and feasibility demonstrated; (2) the scientific and technical merit of the proposed approach for achieving the Phase II objectives; (3) the qualifications of the proposed principal investigator, supporting staff, and consultants; (4) the technological innovation originality, or societal importance of the proposed research; (5) the potential of the proposed research for commercial application; (6) the reasonableness of the budget requested for the work proposed; (7) the adequacy and suitability of the facilities and research environment; and (8) where applicable, the adequacy of (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment.

Award Procedure

Each application receives a dual scientific review by non-NIH scientists. Awards are issued by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). National Research Service Awards: Applications are reviewed for scientific merit by an appropriate study section committee or by an institute review committee. If recommended for approval and a decision is made to make an award, a formal award notice will be sent to the applicant and sponsor. Institutional Awards are issued by the Eunice Kenney Shriver National Institute of Child Health and Human Development (NICHD). All accepted SBIR/STTR applications are evaluated for scientific and technical merit by an appropriate scientific peer review panel and by a national advisory council or board. All applications receiving a priority score compete for the available SBIR/STTR set-aside funds on the basis of scientific and technical merit and the commercial potential of the proposed research, program relevance, and program balance among the areas of research. Contact the headquarters or regional office, as appropriate, for application deadlines, or consult the specific Funding Opportunity Announcement listed in the NIH Guide for Grants and Contracts at: https://grants.nih.gov/funding/searchGuide/nih-guide-to-grants-and-contracts.cfm. General guidance about application due dates may be found at: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Date Range for Approval/Disapproval

> 180 Days. From 6 to 9 months: National Research Service Awards: From 6 to 9 months. SBIR/STTR: approximately 6 months.

Renewals

> 180 Days. Renewal applications are accepted, as described in the relevant Funding Opportunity Announcement (FOA) found at: http://grants.nih.gov/grants/guide/index.html?CFID=50541572&CFTOKEN=87322295&jsessionid=f630f3b44e23db8088b9e5e522459636127 National Research Service Awards: awards may be made for 1, 2, or 3 years. No individual may receive NIH fellowship support at the postdoctoral level for more than 3 years. Institutional Awards may be renewed.

Appeals

Not Applicable. A principal investigator (P.I.) may question the substantive or procedural aspects of the review of his/her application by communicating with the staff of the Institute. A description of the NIH Peer Review Appeal procedures is available on the NIH

web site at:
http://public.csr.nih.gov/ApplicantResources/InitialReviewResultsAppeals/Pages/default.as

Compliance Requirements

Policy Requirements

The following 2CFR policy requirements apply to this assistance listing:
Subpart B, General provisions

Subpart C, Pre-Federal Award Requirements and Contents of Federal Awards

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

The following 2CFR policy requirements are excluded from coverage under this assistance listing:
Not Applicable

Additional Information:

Reports

Program Reports: NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than

the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions. Grantees are allowed a specified period of time to submit required financial and final progress reports (see 45 CFR parts 74.51 and 74.52, 92.40 and 92.41, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

Cash Reports: The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic grantees this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS. For awards issued to foreign institutions after October 1, 2012, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in PMS using subaccounts and payments will be specific to each grant at the time the grantee draws funds.

Progress Reports: Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation (e.g., Research Performance Progress Report [RPPR]) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information. NIH continues to transition to using the RPPR for progress reporting. The RPPR is a federal wide format for the submission of required annual or other interim performance reporting on grant and cooperative agreement awards. The transition to RPPR will be implemented in phases through a module in the eRA Commons. The RPPR is now required for all SNAP and fellowship awards. The PHS 2590 non-competing continuation progress report is currently required for all other NIH awards; however, the RPPR will eventually replace the PHS 2590 paper progress report.

Expenditure Reports: Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. NIH requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons Federal Financial Report (FFR) system allows

participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports. Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. An annual FFR is required for awards to foreign organizations made prior to October 1, 2012 and Federal institutions made prior to October 1, 2013, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date. In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR.

Performance Reports: The grantee institution is required to submit a progress report on an annual basis for each grant award, which includes monitoring of performance.

Audits

Refer to the link below for 2 CFR Subpart F Audit Requirements.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-F
Additional audit requirements:

In addition, grants and cooperative agreements are subject to inspection and audits by DHHS and other Federal officials.

Records

Expenditures and other financial records must be retained for 3 years from the day on which the grantee submits the last expenditure report for the report period.

Regulations, Guidelines, and Literature

42 CFR 52; 42 CFR 66; 45 CFR 74; 45 CFR 92; NIH Grants Policy Statement, (Rev.) March 1, 2001, available on the NIH website at http://grants.nih.gov/grants/policy/nihgps_2001/; NIH Guide to Grants and Contracts, available on the NIH website at http://grants.nih.gov/grants/guide/. Grants will be available under the authority of and administered in accordance with the NIH Grants Policy Statement and Federal regulations at 42 CFR 52 and 42 USC 241; Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant and Cooperative Agreement Applications. Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer (STTR) Grant Applications.

Formula and Matching Requirements

Statutory formula is not applicable to this assistance listing.
Matching requirements are not applicable to this assistance listing.
MOE requirements are not applicable to this assistance listing.

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

Rebekah S. Rasooly, PhD
Director, Division of Extramural Activities DHHS/NIH/NICHD/DEA 6710B Rockledge Drive, Bethesda, MD 20892-7510
rebekah.rasooly@nih.gov
301-827-2599
Website: https://www.nichd.nih.gov/grants-contracts/process-strategies

History

2025
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2022
Published
Child Health and Human Development Extramural Research

2021
Published
Child Health and Human Development Extramural Research

2020
Published
Child Health and Human Development Extramural Research

2019
Published
Child Health and Human Development Extramural Research

2018
Published
Child Health and Human Development Extramural Research

2004
Title Changed
Child Health and Human Development Extramural Research

1998
Title Changed
Center for Research for Mothers and Children

1990
Number Changed
Number changed from 13.865

-
Published
Research for Mothers and Children



Accessibility Contact

⚠ **WARNING**

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SAM.gov

An official website of the U.S. General Services Administration

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Subaward Reporting is live on SAM.gov Show Details
Mar 8, 2025

Scheduled SAM Maintenance Show Details
Mar 18, 2025

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ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing
Overview
Authorizations
Financial Information
Criteria for Applying
Applying for Assistance
Compliance Requirements
Contact Information
History

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

View available opportunities on Grants.gov related to this Assistance Listing

Overview

Objectives

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

Examples of Funded Projects

Fiscal Year 2024: The NICHD program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. Most U.S. women will be affected by one or more gynecological disorders during their lifetime. NICHD manages a broad research portfolio to better understand, treat, and prevent these common, painful, and costly conditions, including endometriosis, uterine fibroids, Polycystic Ovary Syndrome, chronic pelvic pain, and pelvic floor disorders. Uterine fibroids are the most common non-cancerous tumors in women and can cause pain and abnormal bleeding. Sometimes fibroids can make it difficult for a woman to become pregnant or maintain a pregnancy. NICHD-supported scientists are working to develop new prevention and treatment approaches. For example, researchers found that a treatment featuring the drug relugolix could help reduce heavy menstrual bleeding and pain associated with fibroids, without loss in bone mineral density. Another research team is looking at a different drug, an anti-inflammatory medication, which reduced the size of fibroid tumors in mice without side effects. Endometriosis is another gynecologic health condition that can cause severe pain, irregular periods, and infertility. Although the condition runs in families, known genes explain less than two percent of cases. To identify more genes that can account for the condition, researchers recently combined the data from two dozen studies that looked at the whole genomes of almost 61,000 women who had endometriosis, as well as another 702,000 who did not. The scientists found 42 locations within the women's DNA that were linked to endometriosis. A closer look revealed genetic connections to 11 pain conditions, such as migraine, headache, back and spinal pain, and multisite chronic pain. Future studies that reveal more about the shared biology between the pain and inflammatory conditions and endometriosis could lead to new therapies. There is an urgent need for safe, effective, and less invasive infertility treatments, as well as contraception options for both men and women. With support from NICHD, male contraceptive agents are already being tested in humans, and even more promising approaches are being developed in animal models. In a mouse study, researchers identified a potential non-hormonal contraceptive compound that could be taken shortly before sexual activity, with fertility restored the very next day. A recently discovered gene expressed only in the reproductive organs is another promising target for male contraception, because deactivating this gene does not appear to interfere with testosterone production and would not block the hormone's other functions, such as regulating sex drive, building bone mass, and muscle strength. As NIH's leader in pregnancy and maternal health research, NICHD supports studies on clinical treatments

to reduce the risk of pregnancy complications for both pregnant women and their offspring. Through NIH's IMPROVE initiative, NICHD established Maternal Health Research Centers of Excellence to develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity across the country. These Centers, comprising 10 research centers, a data innovation and coordinating hub and an implementation science hub. Together, these institutions will work to design and implement research projects to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. They will focus on populations that experience health disparities, including racial and ethnic minorities, socioeconomically disadvantaged populations, those living in underserved rural areas, sexual and gender minority populations and people with disabilities. The IMPROVE initiative also includes two Challenge prize competition initiatives, in addition to traditional grant funding, that provide innovative approaches to well defined barriers in maternal health care and research engagement. The Rapid Acceleration of Diagnostics (RADx® Tech) for Maternal Health Challenge leverages an innovation funnel approach to accelerate the development of maternal health diagnostic or other remote-sensing technologies (e.g., wearable devices, smartphone-enabled tools) to improve access to care in the postpartum period and complement the use of telehealth in areas without sufficient maternity care. The Connecting the Community for Maternal Health Challenge aims to address the structural barriers faced by community and advocacy organizations to conduct maternal health research by helping them build effective research infrastructure and capacity.

Fiscal Year 2025: NICHD continues to improve understanding of the effects of COVID-19 infection and disease during pregnancy, in the postpartum, during lactation, and in newborns, as well as its long term impact, and continues to work toward inclusion of pregnant and lactating people in SARS-CoV-2 vaccine research. A recent study found that by late 2022, widespread COVID-19 vaccination of pregnant people likely halted a spike in the preterm birth rate that began at the start of the pandemic. Another study found that preterm infants receive similar levels of maternal antibody protection as term infants after maternal COVID-19 vaccination. NICHD's research networks play a leading role in clinical research advances for maternal and neonatal health. For example, in a large, multi-country clinical trial, researchers showed that a single dose of the antibiotic azithromycin can reduce the risk of postpartum sepsis and death by one third among women who deliver vaginally. For vulnerable infants, scientists found that extremely preterm infants who were fed fortified human milk grew longer and more rapidly and had larger head circumferences compared with extremely preterm infants fed unfortified human milk. The findings provide support for future studies on the potential benefits of human milk fortification in preventing malnutrition among infants born at 28 weeks or younger. NICHD is represented on the executive and steering committees of the NIH-wide Climate Change and Health Initiative aiming to reduce the health threats posed by climate change across the lifespan. The health effects of climate and environmental changes can affect many stages of a women's reproductive life,

impacting the health of future generations. Growing evidence suggests that heat stress negatively influences fetal growth and pregnancy outcomes, as two recent studies from NICHD's Global Network for Women's and Children's Health illustrate. One study, which evaluated more than 120,000 pregnant women in India and Pakistan, found a higher incidence of pregnancy-related high blood pressure, severe preeclampsia, preterm birth, and low birth weight with greater temperatures. Another study, conducted in Pakistan, found that exposure to excessive heat in early pregnancy was linked to lower infant lengths and head circumferences at birth. The findings also suggest that nutritional supplementation early in pregnancy may help offset some of the effects of heat stress. Research on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth. This research program also supports the evidence base for pediatric medicine, through clinical studies in pharmacology, infectious diseases, endocrinology, trauma and critical illness, and other aspects of health throughout infancy, childhood, and adolescence. Although children have distinct medical needs, and their physiology is not the same as adults, medical practices are often extrapolated from adult research without adequate study specifically in children. The Collaborative Pediatric Critical Care Research Network is funded by NICHD to conduct large-scale, multicenter randomized controlled trials to provide the research needed to make the best medical decisions for children in real-time while they are in the pediatric intensive care unit. Recent research supported through NICHD uncovered links between severe sepsis—a factor in 60 percent of child deaths worldwide—and certain genes related to the child's immune system. These findings are opening the way for genetic screening to tailor sepsis treatment according to a child's specific immune system functioning. NICHD also administers eight grants to refine technologies for early diagnosis of severe illnesses resulting from SARS-CoV-2 infection in children, including Multisystem Inflammatory Syndrome in Children (MIS-C). NICHD-supported researchers recently found that children with COVID-19 who develop MIS-C have unique biochemical indicators of cell injury and cell death, providing a pathway to develop tests that can identify children with MIS-C. Other researchers identified the mechanism by which MIS-C appears to cause shock in children. Inflammation of the blood vessels prevents the vessels from constricting, resulting in low blood pressure and circulation. This finding indicates that medications that constrict the blood vessels may be a preferred treatment option. NICHD supports a broad spectrum of research that seeks to prevent and treat pediatric injuries. To minimize the impact of head injury in youth football, researchers compared the magnitude, frequency, and location of head impacts among youth and college football players to inform the development of age-appropriate guidelines for helmet design and other prevention measures.

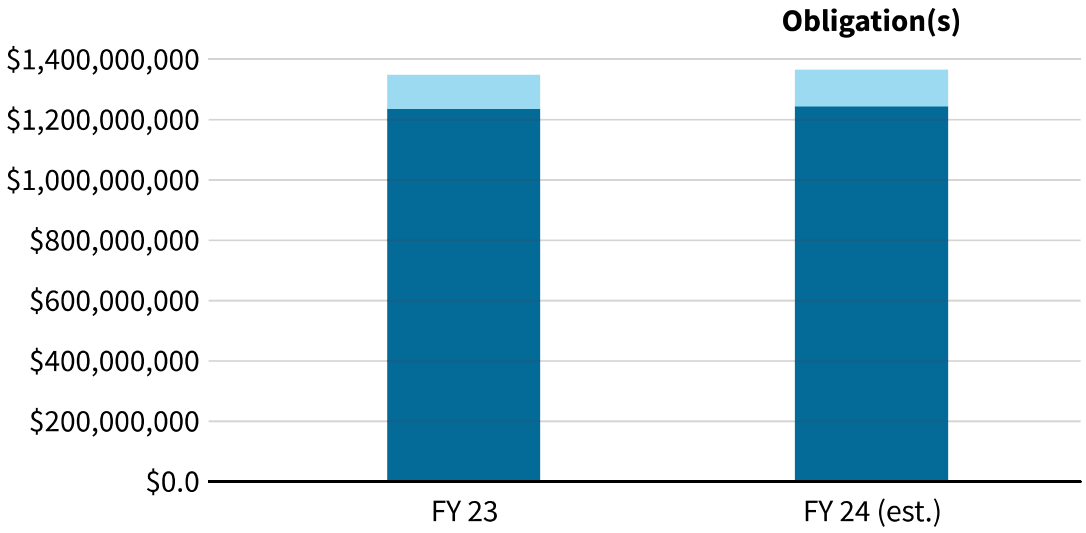
Authorizations

Public Health Service Act, Section 301, 448 and 487, as amended, Public Laws 78-410 and 99-158, as amended, 42 U.S.C. 241; 42 U.S.C. 285g; 42 U.S.C. 288; Small Business

Research and Development Enhancement Act of 1992, Public Law 102-564, Public Law 118-47

Financial Information

These funding amounts do not reflect the award amounts that are displayed on USASpending.gov



Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
☐ **Project Grants Total**	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**
For FY 2023, of the $1,233,369,249 for Total Research Grants, $51,684,492 was for SBIR/STTR activities and awards. For FY 2024, of the $1,241,888,972 for Total Research Grants, $51,395,322 was for SBIR/STTR activities and awards. For FY 2025, of the estimated $1,247,152,000 for Total Research Grants, $51,136,000 is planned for SBIR/STTR activities and awards. NOTE: these amounts	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**

Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
do not include training, R&D contracts of operating funds.			
☐ Cooperative Agreements (Discretionary Grants) Total	**$111,889,797**	**$120,423,704**	**$120,500,000**
Totals	**$1,345,259,046**	**$1,362,312,676**	**$1,367,652,000**

Range and Average of Financial Assistance

For research project grants, fiscal year 2024, range is $50,000 to $5,000,000; average is $534,606. Individual research fellowship awards: Basic stipend (first year beyond the doctoral degree) of approximately $45,000. The sponsoring institution will be provided, on application, with an allowance of up to approximately $8,000 per year to help defray the cost of training. No dependency allowances. SBIR: Average Phase I awards are for approximately $225,000 (grant activity R43 - for up to six months); Phase II awards may be made for amounts up to $1,500,000 (grant activity R44 - for up to two years).

Accomplishments

Fiscal Year 2024: Budget Actuals: Fiscal year 2024 competing and noncompeting research project grants actuals are 1,839. Of this number, 70 were SBIR/ STTR awards. Exactly 61 research centers were awarded. Exactly 423 other research grants were awarded. There were institutional training grants to support 389 trainees that were awarded in fiscal year 2024. The individual training award were 292 for fiscal year 2024.

Fiscal Year 2025: Budget Request: Fiscal year 2025 planned competing and noncompeting research project grants are expected to be 1,859. Of this number, 89 are planned to be SBIR/ STTR awards. An estimated 66 research centers are planned to be awarded. There are plans for 411 other research grants to be awarded. There are plans for institutional training grants to support 409 trainees to be awarded in fiscal year 2025. The individual training awards are estimated at 299 for fiscal year 2025.

Account Identification

75-0844-0-1-552-DHHS/NIH/ Eunice Kennedy Shriver National Institute

Criteria for Applying

Types of Assistance

B - Project Grants, B - Cooperative Agreements (Discretionary Grants)

Credentials and Documentation

Applicants should submit electronically via Grants.gov as directed in the relevant NIH Funding Opportunity Announcement. All required forms specified in the application kit are to be completed by the applicant and submitted with the application package. National Research Service Award: Individual Award: The applicant's academic record, research experience, citizenship, and institution sponsorship should be documented in the application. Institutional Award: the applicant organization must show the objectives, methodology, and resources for the research training program, the qualifications and experience of directing staff, the criteria to be used in selecting individuals for awards, and a detailed budget and justification for the amount of grant funds requested. For-profit organizations' costs are determined in accordance with 48 CFR, Subpart 31.2 of the Federal Acquisition Regulations. For other grantees, costs will be determined by HHS Regulations, 45 CFR, Part 74, Subpart Q. For SBIR and STTR grants, applicant organization (small business concern) must present in a research plan an idea that has potential for commercialization and furnish evidence that scientific competence, experimental methods, facilities, equipment, and funds requested are appropriate to carry out the plan. 2 CFR 200, Subpart E - Cost Principles applies to this program.

Applicant Eligibility

Designations

State (includes District of Columbia, public institutions of higher education and hospitals), Local (includes State-designated lndian Tribes, excludes institutions of higher education and hospitals, Public nonprofit institution/organization (includes institutions of higher education and hospitals), Individual/Family, Private nonprofit institution/organization (includes institutions of higher education and hospitals)

Universities, colleges, medical, dental and nursing schools, schools of public health, laboratories, hospitals, State and local health departments, other public or private institutions, both nonprofit and for-profit, and individuals. National Research Service Award: Support is provided for academic and research training only, in health and

health-related areas that are periodically specified by the National Institutes of Health. Individuals with a professional or scientific degree are eligible (M.D., Ph.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree). Predoctoral research training grants to institutions are also supported. Proposed study must result in biomedical or behavioral research training in a specified shortage area and which may offer opportunity to research health scientists, research clinicians, etc., to broaden their scientific background or to extend their potential for research in health-related areas. Applicants must be citizens of the United States or be admitted to the United States for permanent residency; they also must be nominated and sponsored by a public or private institution having staff and facilities suitable to the proposed research training. Domestic nonprofit organizations may apply for the institutional NRS grant. SBIR: SBIR grants can be awarded only to domestic small businesses (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed, and have no more than 500 employees). Primary employment (more than one- half time) of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In both Phase I and Phase II, the research must be performed in the U.S. or its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council. STTR grants can be awarded only to domestic small business concerns (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed and have no more than 500 employees) which "partner" with a research institution in cooperative research and development. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent by the research institution. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council.

Beneficiary Eligibility

Designations

Individual/Family, Private nonprofit institution/organization, Student/Trainee, Scientist/Researchers, State, U.S. Citizen, Local, Public nonprofit institution/organization

Any nonprofit or for-profit organization, company, or institution engaged in biomedical or biobehavioral research.

Length and Time Phasing of Assistance

Awards are usually made annually with no project period to exceed 5 years in length. National Research Service Awards: From 1 to 3 years. SBIR: Phase I awards are generally for 6 months; Phase II awards normally may not exceed 2 years. STTR Phase I awards are generally for 1 year; Phase II awards normally may not exceed 2 years. Method of awarding/releasing assistance: Each year, submitted progress reports for awarded grants are reviewed, and if satisfactory progress is demonstrated, a Notice of Grant Award is issued.

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

Grantee agrees to administer the grant in accordance with the regulations and policies governing the research grant programs of the Public Health Service as stated in the terms and conditions on the application for the grant. National Research Service Awards: Awarded to individuals for full-time research training in specified behavioral and biomedical shortage areas. Awardees may utilize some of their time in academic and clinical duties if such work is closely related to their research training. Awards may be made to institutions to enable them to make NRS awards to individuals selected by them. Each individual awardee is obligated upon termination of the award to comply with certain service and payback provisions. SBIR Phase I grants (of approximately 6-months' duration) are to establish the technical merit and feasibility of a proposed research effort that may lead to a commercial product or process. Phase II grants are for the continuation of the research initiated in Phase I and which are likely to result in commercial products or processes. STTR Phase I grants (normally of 1- year duration) are to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort that has potential for commercial application. Phase II funding is based on results of research initiated in Phase I and scientific and technical merit and commercial potential on Phase II application.

Applying for Assistance

Deadlines

Contact the headquarters or regional location, as appropriate for application deadlines

Preapplication Coordination

Preapplication coordination is not applicable. Environmental impact information is not required for this program. This program is excluded from coverage under E.O. 12372.

Application Procedures

2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards applies to this program.
National Research Service Award: Prior to formal application, an individual must arrange for acceptance at a sponsoring institution by a sponsor who will supervise the training. Individuals must be sponsored by a domestic or foreign institution. SBIR/STTR: Same as for grants (above). Applications are submitted electronically via Grants.gov following the general guidance provided at: http://grants.nih.gov/grants/forms.htm and the specific instructions for the respective Funding Opportunities Announcement which may be found at: https://grants.nih.gov/funding/index.htm

Criteria for Selecting Proposals

The major elements in evaluating proposals include assessments of the significance of the proposed research; approach; innovation; investigators; and environment. The following criteria will be used in considering the scientific and technical merit of SBIR/STTR Phase I grant applications: (1) The soundness and technical merit of the proposed approach; (2) the qualifications of the proposed principal investigator, supporting staff, and consultants; (3) the technological innovation of the proposed research; (4) the potential of the proposed research for commercial application; (5) the appropriateness of the budget requested; (6) the adequacy and suitability of the facilities and research environment; and (7) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment. Phase II grant applications will be reviewed based upon the following criteria: (1) The degree to which the Phase I objectives were met and feasibility demonstrated; (2) the scientific and technical merit of the proposed approach for achieving the Phase II objectives; (3) the qualifications of the proposed principal investigator, supporting staff, and consultants; (4) the technological innovation originality, or societal importance of the proposed research; (5) the potential of the proposed research for commercial application; (6) the reasonableness of the budget requested for the work proposed; (7) the adequacy and suitability of the facilities and research environment; and (8) where applicable, the adequacy of (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment.

Award Procedure

Each application receives a dual scientific review by non-NIH scientists. Awards are issued by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). National Research Service Awards: Applications are reviewed for scientific merit by an appropriate study section committee or by an institute review committee. If recommended for approval and a decision is made to make an award, a formal award notice will be sent to the applicant and sponsor. Institutional Awards are issued by the Eunice Kenney Shriver National Institute of Child Health and Human Development (NICHD). All accepted SBIR/STTR applications are evaluated for scientific and technical merit by an appropriate scientific peer review panel and by a national advisory council or board. All applications receiving a priority score compete for the available SBIR/STTR set-aside funds on the basis of scientific and technical merit and the commercial potential of the proposed research, program relevance, and program balance among the areas of research. Contact the headquarters or regional office, as appropriate, for application deadlines, or consult the specific Funding Opportunity Announcement listed in the NIH Guide for Grants and Contracts at: https://grants.nih.gov/funding/searchGuide/nih-guide-to-grants-and-contracts.cfm. General guidance about application due dates may be found at: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Date Range for Approval/Disapproval

> 180 Days. From 6 to 9 months: National Research Service Awards: From 6 to 9 months. SBIR/STTR: approximately 6 months.

Renewals

> 180 Days. Renewal applications are accepted, as described in the relevant Funding Opportunity Announcement (FOA) found at: http://grants.nih.gov/grants/guide/index.html?CFID=50541572&CFTOKEN=87322295&jsessionid=f630f3b44e23db8088b9e5e522459636127 National Research Service Awards: awards may be made for 1, 2, or 3 years. No individual may receive NIH fellowship support at the postdoctoral level for more than 3 years. Institutional Awards may be renewed.

Appeals

Not Applicable. A principal investigator (P.I.) may question the substantive or procedural aspects of the review of his/her application by communicating with the staff of the Institute. A description of the NIH Peer Review Appeal procedures is available on the NIH

web site at:
http://public.csr.nih.gov/ApplicantResources/InitialReviewResultsAppeals/Pages/default.as

Compliance Requirements

Policy Requirements

The following 2CFR policy requirements apply to this assistance listing:
Subpart B, General provisions

Subpart C, Pre-Federal Award Requirements and Contents of Federal Awards

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

The following 2CFR policy requirements are excluded from coverage under this assistance listing:
Not Applicable

Additional Information:

Reports

Program Reports: NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than

the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions. Grantees are allowed a specified period of time to submit required financial and final progress reports (see 45 CFR parts 74.51 and 74.52, 92.40 and 92.41, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

Cash Reports: The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic grantees this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS. For awards issued to foreign institutions after October 1, 2012, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in PMS using subaccounts and payments will be specific to each grant at the time the grantee draws funds.

Progress Reports: Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation (e.g., Research Performance Progress Report [RPPR]) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information. NIH continues to transition to using the RPPR for progress reporting. The RPPR is a federal wide format for the submission of required annual or other interim performance reporting on grant and cooperative agreement awards. The transition to RPPR will be implemented in phases through a module in the eRA Commons. The RPPR is now required for all SNAP and fellowship awards. The PHS 2590 non-competing continuation progress report is currently required for all other NIH awards; however, the RPPR will eventually replace the PHS 2590 paper progress report.

Expenditure Reports: Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. NIH requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons Federal Financial Report (FFR) system allows

participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports. Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. An annual FFR is required for awards to foreign organizations made prior to October 1, 2012 and Federal institutions made prior to October 1, 2013, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date. In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR.

Performance Reports: The grantee institution is required to submit a progress report on an annual basis for each grant award, which includes monitoring of performance.

Audits

Refer to the link below for 2 CFR Subpart F Audit Requirements.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-F
Additional audit requirements:

In addition, grants and cooperative agreements are subject to inspection and audits by DHHS and other Federal officials.

Records

Expenditures and other financial records must be retained for 3 years from the day on which the grantee submits the last expenditure report for the report period.

Regulations, Guidelines, and Literature

42 CFR 52; 42 CFR 66; 45 CFR 74; 45 CFR 92; NIH Grants Policy Statement, (Rev.) March 1, 2001, available on the NIH website at http://grants.nih.gov/grants/policy/nihgps_2001/; NIH Guide to Grants and Contracts, available on the NIH website at http://grants.nih.gov/grants/guide/. Grants will be available under the authority of and administered in accordance with the NIH Grants Policy Statement and Federal regulations at 42 CFR 52 and 42 USC 241; Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant and Cooperative Agreement Applications. Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer (STTR) Grant Applications.

Formula and Matching Requirements

Statutory formula is not applicable to this assistance listing.
Matching requirements are not applicable to this assistance listing.
MOE requirements are not applicable to this assistance listing.

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

Rebekah S. Rasooly, PhD
Director, Division of Extramural Activities DHHS/NIH/NICHD/DEA 6710B Rockledge Drive, Bethesda, MD 20892-7510
rebekah.rasooly@nih.gov
301-827-2599
Website: https://www.nichd.nih.gov/grants-contracts/process-strategies

History

2025
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2022
Published
Child Health and Human Development Extramural Research

2021
Published
Child Health and Human Development Extramural Research

2020
Published
Child Health and Human Development Extramural Research

2019
Published
Child Health and Human Development Extramural Research

2018
Published
Child Health and Human Development Extramural Research

2004
Title Changed
Child Health and Human Development Extramural Research

1998
Title Changed
Center for Research for Mothers and Children

1990
Number Changed
Number changed from 13.865

-
Published
Research for Mothers and Children



Accessibility Contact

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SAM.gov

An official website of the U.S. General Services Administration

EXHIBIT 31

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF PRIYA NAMBISAN

I, Priya Nambisan, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a Associate Professor at the University of Wisconsin-Milwaukee. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am an Associate Professor at the University of Wisconsin-Milwaukee with 20 years of experience in academia. I previously held roles in three other higher education institutions – UAlbany, SUNY, and George Mason University. I have a Master's Degree in nutrition from Syracuse University and PhD in Communication from Rensselaer Polytechnic Institute and did a one year post-doc in Health Informatics at University of Wisconsin-Madison.

4. I lead two laboratories - one focused on Social media and health called SMAHRT (Social Media And Health Research & Training) lab and another one focused on older adults and technology called ARDT (Aging Research & Digital Technologies) lab at University of Wisconsin – Milwaukee. I have served as a Principal Investigator (PI) or Co-Investigator on numerous funded projects over the course of my career. I also currently serve on NIH small business SBIR/STTR study section, which is a study section focused on technological innovations for improving minority health and eliminating health disparities.

5. I am providing this declaration to detail my experience with terminations of NIH-funded grants historically, and how that experience has changed since late January of 2025.

6. I am also providing this declaration to explain the impacts of delays in the grant review and renewal process and of grant terminations on my staff, my research, and the people who benefit from it.

7. The termination severely impacts my research and my lab, specifically my SMAHRT lab, as much of the work done by students and hourly pay staff had to be stopped. Social media's impact on mental health of adolescents and youth is an important, time critical and relevant topic for research. Terminating our study could limit our ability to develop appropriate interventions to mitigate the negative impact of social media use on our children (including mental health issues and suicidality).

Reliance on NIH Funding

8. In fiscal year 2024, my lab received funding through NIH to support one project, totaling $1.3 million. I received these funds for a grant, which runs from September 2024 to July 2027. This is an important study with critical societal benefits and the unique data collection

method we are using can be applied to different population groups, which would substantially improve our understanding of how social media is impacting the mental health of our children.

9. My lab employs three hourly workers who are funded primarily through this NIH grant, whose employment must be terminated with termination of this grant. One of these is a PhD student who work in my lab and is funded primarily through this NIH grant.

Typical Processes for NIH Grant Awards

10. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-5 year terms, though some may be longer and others may be shorter.

11. Although the life of the grant is often longer, funding is only provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the state project goals, in my experience such renewals are typically granted.

12. These regular cycles and predictable renewals are essential for the continuity of funding for my lab and my research. In my lab, we work with constantly changing technologies which require substantial amount of training, so that student workers can work on the data being collected. All this requires planning, budgeting and funding as this allows it to move it substantially forward.

13. In my experience, termination of an active grant is also extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious

scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Irregularities in Grant Terminations

14. For one of the previously approved grants for which I am principal investigator, we recently received a letter from NIH purporting to terminate the grant because it does not "effectuate agency priorities" because The letter went on to state, "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." I was not referred to any new policy statement or regulation that described the new agency priorities.

15. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that NIMH's role is to advance basic science of brain, genomics, and behavior to understand mental illnesses; chart mental illness trajectories to determine when, where, and how to intervene; highlight efforts to improve preventive and therapeutic interventions; bring knowledge to practice, improvements to services, and better outcomes to individuals. My project advances those goals by understanding how, when and why social media use impact suicidality among adolescents and youth. The study would inform parents how to protect their children from the negative impact of social media and prevent suicides. The study also has implications on timely interventions by mental health providers in preventing suicide among those adolescents and youth who are spending unhealthy amount of time on social media platforms. This is not a "research program based on gender identity" but a study on suicide prevention.

Comparisons Across Administrations

16. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

17. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

18. Due to the delays and funding uncertainty, and having sought alternative sources of funding and failed to secure them, I have been forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment;

c. Stop ongoing experiments, compromising time-sensitive components of the research. I was in the process of recruiting participants and had started data collection process, this getting stopped midway is going to impact the study

protocol. In addition, there is urgency to complete this research as it might reveal important aspects regarding social media use and how it impacts suicide;

d. Delay work on clinical translation, including potential therapeutic development such as suicide prevention intervention for adolescents who consume social media content and is mentally impacted by it.

19. Students working in my lab who are relying on research conducted there to obtain their PhDs are likely to see disruption in their progression and career development.

20. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

21. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

Priya Nambisan

Date: April 1, 2025

EXHIBIT 32

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

laintiffs

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF KRISTIAN O'CONNOR

I, Kristian O'Connor, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Interim Vice Provost for Research and Dean of the Graduate School of the University of Wisconsin-Milwaukee. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the University of Wisconsin-Milwaukee staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Interim Vice Provost for Research and Dean of the Graduate School of the University of Wisconsin-Milwaukee, a position I have held since 2023. As Interim Vice Provost for Research and Dean of the Graduate School, I serve as UWM's Chief Research Officer and have oversight of the Office of Research, which is responsible for the administration of research activity, oversight of research policy, and compliance with federal and state

requirements. The Office of Research also provides pre- and post-award administrative support for sponsored projects. Prior to holding this position, I was the Associate Vice Provost for Research and have been a faculty member at UWM since 2002. As a faculty member, I have served as PI on several NIH awards, and in my role in the Office of Research I am currently the site PI for an inter-institutional NIH CTSA grant.

4. The University of Wisconsin-Milwaukee's statutory mission includes promoting the search for knowledge by offering research programs with emphasis on state and national needs. Wis. Stat. § 36.01(1).

5. The University of Wisconsin-Milwaukee is an R1 Research Institution with $65M total research expenditures in FY24, which includes $11.1M in funding from HHS.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts the University of Wisconsin-Milwaukee by interrupting critical health related research activities that lead to impactful research outcomes.

Reliance on NIH Funding

8. In fiscal year 2024, the University of Wisconsin-Milwaukee received funding through the National Institutes of Health ("NIH") to support dozens of projects, totaling $7.9M.

9. The University of Wisconsin-Milwaukee receives NIH grants across a variety of institutes encompassed within the NIH, including NIDA, NIGMS, NIMH, NIAAA, NIA, NIBIB, NICHHD, NINDS, and NCI.

10. Through those NIH grants, the University of Wisconsin-Milwaukee funds 20 Principal- and co-investigators.

11. The work done by the University of Wisconsin-Milwaukee on NIH funded projects provides education and training in Biomedical Engineering, Mechanical Engineering, Biology, Public Health and Health Sciences, Chemistry, Psychology, and other programs.

12. The University of Wisconsin-Milwaukee provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Wisconsin economy.

Typical Timeline and Processes for NIH Grant Awards

13. The Office of Research at the University of Wisconsin-Milwaukee works with researchers to submit grant applications and tracks grant applications and awards.

14. Based on my work as Interim Vice Provost of Research and formerly Associate Vice Provost of Research I have an understanding of the NIH grant process.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at the University of Wisconsin-Milwaukee relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 9 months of submission.

20. Once a grant receives a score, the University of Wisconsin-Milwaukee is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Terminations of NIH Grants

21. Since March 21, 2025, the University of Wisconsin-Milwaukee has had two NIH grants terminated, covering four projects. These grants funded studies on suicide prevention, as well as substance use and violence prevention.

22. The terminations received as of April 1, 2025, are attached hereto as Exhibit A.

23. These terminations will result in the loss of significant research money to the University of Wisconsin-Milwaukee.

24. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my 23 years working at the University of Wisconsin-Milwaukee, I have not seen this language previously used to cancel grants.

25. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, the University of Wisconsin-Milwaukee had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was the University of Wisconsin-Milwaukee provided with any updated "agency priorities" with which its research must align.

26. The terminated grants focus on critical issues impacting public health, including a study on suicide prevention, as well as a study on substance use and violence prevention.

Comparisons Across Administrations

27. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

28. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

29. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

30. Several shared research cores have seen decreased usage due to grant uncertainty, and one facility temporarily reduced staff hours due to budget delays.

Irreparable Harm

31. The terminations have disrupted ongoing research, as well as setting back the University of Wisconsin-Milwaukee for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

32. Delays have also disrupted community services, student opportunities, and public programs.

33. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

34. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



Kristian O'Connor

Date: April 2, 2025

EXHIBIT A
TO DECLARATION OF KRISTIAN O'CONNOR

Tillison, Kevin <ktillison@vt.edu>
Monday, March 24, 2025 7:41 AM
Ryan C Shorey <shorey@uwm.edu>; UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Brem, Meagan <mbrem@vt.edu>
Notice of Termination: Subaward 412980-19E63 with Virginia Tech

Dear Dr. Shorey and colleagues,

Virginia Tech has received official notice of termination for grant 1R21 AA031548-01A1, entitled Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study, in accordance with 2 C.F.R. § 200.340(a)(2). As a result, we are unable to proceed with the subaward agreement. The effective date of the termination was March 20, 2025.

We appreciate your collaboration and interest in working with Virginia Tech. Please feel free to reach out if you have any questions or require further clarification.

Best Regards,

Kevin

Kevin A. Tillison, PhD
Contracts Negotiator
Virginia Tech | Office of Sponsored Programs | Federal Agency Updates
300 Turner Street NW, Suite 4200
Blacksburg, VA 24061
(540) 231-9887 | ktillison@vt.edu



Tillison, Kevin <ktillison@vt.edu>
Thursday, January 16, 2025 11:09 AM
grant-notice@uwm.edu <grant-notice@uwm.edu>
Subrecipient Signature Request: Subaward 412980-19E63 with Virginia Tech

Greeting from Virginia Tech,

Attached is the Research Subaward Agreement between Virginia Tech and the University of Wisconsin Milwaukee for the National Institute on Alcohol Abuse and Alcoholism funded research entitled: Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study.

Please review the terms and conditions and if you have any questions or concerns please let me know.

If the terms and conditions are acceptable, please have the subaward signed by an authorized official and return to my attention a partially executed agreement.

Also, prior to signature, please complete the Attachment 3B.

Thank you,

Kevin (internal reference: A5PSOEUK)

Kevin A. Tillison, PhD
Contracts Negotiator
Virginia Tech | Office of Sponsored Programs
300 Turner Street NW, Suite 4200
Blacksburg, VA 24061
(540) 231-9887 | ktillison@vt.edu



National Institutes of Health
Office of Extramural Research

March 20, 2025

Trudy M. Riley
Virginia Polytechnic Institute & State University
ospdirector@vt.edu

Dear Trudy M. Riley:

Effective with the date of this letter, funding for Project Number 1R21 AA031548-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 17, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, National Institute on Alcohol Abuse and Alcoholism
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Friday, March 21, 2025 11:35 AM
UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Grant Termination Notification



3/21/2025

Jeremy Miner
University Of Wisconsin Milwaukee
GRANT-NOTICE@UWM.EDU

Dear Jeremy Miner:

Effective with the date of this letter, funding for Project Number 1R01MH135498-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/5/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6]

no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *SAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 33

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF RYAN SHOREY

I, Ryan Christopher Shorey, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am an Associate Professor at the University of Wisconsin-Milwaukee. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am an Associate Professor at the University of Wisconsin-Milwaukee. I have been a faculty member at the University of Wisconsin-Milwaukee since August 2018, where I conduct research and teach undergraduate and graduate students. Prior to that, I was a faculty member at Ohio University from Fall 2014-Spring 2018. I completed my PhD in Clinical Psychology at the University of Tennessee-Knoxville (American Psychological Association accredited; 2014).

4. I lead a laboratory focused on the impact of alcohol use on intimate partner and sexual violence among LGBTQ+ and young adult populations at the University of Wisconsin-Milwaukee. I have served as a Principal Investigator (PI) or Co-Investigator on numerous National Institutes of Health ("NIH") funded projects over the course of my career. I also currently serve as a standing member on The Social Psychology, Personality and Interpersonal Processes (SPIP) Study Section at NIH, which is a study section focused on grant applications examining the socio-personal, interpersonal, and psychological aspects of health and well-being across the lifespan.

5. I am providing this declaration to detail my experience with terminations of NIH-funded grants historically, and how that experience has changed since late January of 2025.

6. I am also providing this declaration to explain the impacts of delays in the grant review and renewal process and of grant terminations on my staff, my research, and the people who benefit from it.

7. The terminations severely impact me and my lab by completely halting critical public health research on the intersections of alcohol use and intimate partner and sexual violence; terminating the employment of a full-time project coordinator; stopping training in critical research skills for four PhD students in Clinical Psychology; halting research opportunities for undergraduate students; and causing irreparable career harm.

Reliance on NIH Funding

8. In fiscal year 2024, my lab received funding through NIH as PI and Co-PI to support five projects, totaling approximately $1,378,747. I received these funds under six grants, which run from 6 6/1/19–5/31/25; 7/22/22-3/31/27; 6/1/23–5/31/26; 8/17/23–5/31/28; 9/17/24-

8/31/26; 8/1/23-7/31/25. Critically, the dates of the awards were staggered intentionally to preserve funding for continuity of research lab operations.

9. My lab employs one worker who is funded primarily through NIH grants, whose employment I will have to terminate if my grants are terminated. I also have PhD students who work in my lab and are funded primarily through NIH, and who are relying on the work done there to complete their own research and earn their degrees. These students will lose funding and critical training opportunities if NIH funding is cutoff.

Typical Processes for NIH Grant Awards

10. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-5 year terms, though some may be longer and others may be shorter.

11. Although the life of the grant is often longer, funding is only provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the state project goals, in my experience such renewals are typically granted.

12. These regular cycles and predictable renewals are essential for the continuity of funding for my lab. Without this predictability, we are unable to hire study staff, have available supplies for studies, and unable to enroll research participants into studies as we transition from one year to the next. This severely disrupts our ability to conduct important scientific research on critical public health problems.

13. In my experience, termination of an active grant is also extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Irregularities in Grant Terminations

14. For two of the previously approved grants for which I am principal investigator, we recently received a letter from NIH purporting to terminate the grant because it does not "effectuate agency priorities." The letter went on to state, "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." I was not referred to any new policy statement or regulation that described the new agency priorities.

15. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that the National Institute on Alcohol Abuse and Alcoholism's role is to, in part, "Identify Patterns, Trends, and Public Health Impact of Alcohol Misuse" and "…support epidemiological research to identify and track patterns of alcohol use and misuse, drinking-related outcomes and disparities, and individual and environmental variables that confer risk or resilience." My projects advance those goals by focusing on the alcohol-related outcome of sexual assault and intimate partner violence, serious and prevalent public health problems that impacts all Americans. In our grants, we are examining the conditions under which alcohol-related sexual assault and intimate partner violence are most likely to occur, which will have significant implications for addressing these costly public health problems. In addition, our grants focus on

both individual and environmental variables that confer risk and resilience for alcohol use and adverse alcohol-related outcomes. We are examining the impact of various daily and distal stressors on risk for alcohol use, how sexual assault and intimate partner violence impact subsequent alcohol use, and how social support may act as a resilience factor for alcohol use and the adverse impacts of alcohol use. This is not a "research program based on gender identity" but a study on substance use and violence prevention.

Comparisons Across Administrations

16. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses and awards. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

17. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

18. Due to the delays and funding uncertainty, and having sought alternative sources of funding and failed to secure them, I have been forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment;

c. Stop ongoing research, compromising time-sensitive components of the research. For example, I have had to stop two longitudinal studies, pausing the research participation of dozens of people who consented to engage in this research. This will result in significant disruptions to the overall quality of the science and difficulty translating this critical work to into effective public health initiatives designed to improve the lives of Americans.

19. Students working in my lab who are relying on research conducted there to obtain their PhDs are likely to see disruptions in their progression and career development.

20. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

21. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

_____

Ryan C. Shorey

Date: April 1, 2025

EXHIBIT 34

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF PETER G. BARR-GILLESPIE

I, Peter G. Barr-Gillespie, Ph.D, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Executive Vice President and Chief Research Officer of Oregon Health & Science University ("OHSU"). In addition, I am a Professor with the OHSU Oregon Hearing Research Center and an affiliated scientist with the Vollum Institute. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the OHSU staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Executive Vice President and Chief Research Officer at OHSU, having held that position or an equivalent one for seven and a half years. I am also a Professor in the Department of Otolaryngology, and I have been running a research lab at OHSU since 1999. Prior to that I was an Assistant, then Associate Professor in the Department of Physiology at

Johns Hopkins University, where I was from 1993-1999. I received my postdoctoral training in neuroscience from Dr. James Hudspeth at the University of California San Francisco from 1988-1989 and at the University of Texas Southwestern Medical Center from 1989-1993. I earned a BA in chemistry from Reed College in 1981 and a PhD in pharmacology from the University of Washington in 1988.

4. OHSU's statutory mission is to provide healthcare, education and conduct research that supports the people of the State of Oregon.

5. OHSU houses a robust research program with approximately 1,415 faculty investigators and 262 postdoctoral scholars.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts OHSU by cutting off funding to research faculty members, preventing their ability to continue to support their own salaries and those of the research staff in their labs. This funding shortfall will both lead to faculty layoffs and negatively impact OHSU's budget to support research.

Reliance on NIH Funding

8. In fiscal year 2024, OHSU received funding through the National Institutes of Health ("NIH") to support 784 projects, totaling $353.33 million.

9. OHSU receives NIH grants across a variety of institutes encompassed within the NIH, including National Institute of Allergy & Infectious Diseases, National Institute on Aging, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute of Neurological Disorders and Stroke, National Eye Institute, National Institute of General Medical Science, National Human Genome Research Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Mental Health, National Institute on Deafness and Other Communication Disorders, and the National Institute of Dental and Craniofacial Research, amongst others.

10. Through those NIH grants, OHSU funds approximately 1,415 researchers.

11. The work done by OHSU on NIH funded projects provides education and training in PhD-granting graduate programs in Behavioral Neuroscience, Biomedical Engineering, Biomedical Sciences, Clinical Psychology, and Neuroscience.

12. OHSU provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the OREGON economy.

13. As an example of impact on OHSU infrastructure, we have submitted a C06 construction grant to the NIH to support construction of a Biosafety Level 3 (BSL-3) laboratory, but that project is on hold while the grant review has been postponed.

Typical Timeline and Processes for NIH Grant Awards

14. The Office of Proposal & Award Management at OHSU works with researchers to submit grant applications and tracks grant applications and awards.

15. Based on my work as Professor and Chief Research Officer, I have an understanding of the NIH grant process based on my 25 years in those roles.

16. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

18. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

19. The process for competitive renewals is very similar, but it is even more likely for a grant that has been funded in the past to be renewed.

20. The budget process at OHSU relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within six months of submission.

21. Once a grant receives a score, OHSU is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

22. Since late January 2025, OHSU has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

23. OHSU has not received formal notice of changes for many of these grants. For others, OHSU has gotten only a notification that proposals are "paused" or "under review."

24. As of March 31, 2025, OHSU has approximately 280 proposals totaling $731.6 million awaiting NIH study section review.

25. As of March 31, 2025, OHSU has 70 proposals totaling $172.4 million that received fundable scores, awaiting NIH advisory council and Notice of Award.

26. As of March 31, 2025, OHSU has 90 proposals totaling $194.9 million that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

27. Since March 24, 2025, OHSU has received a notice of termination of one NIH grant awarded directly to OHSU, as well as seven subawards issued from other institutions which had their NIH award terminated. We have received multiple notifications from NIH that additional terminations are imminent.

28. The notice of termination received as of March 24, 2025 is attached hereto as Exhibit A. The overall goal of this project is to utilize the nonhuman primate model to identify the mechanisms responsible for the metabolic disorders associated with long COVID. The termination states, "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

29. The notice of termination for one of the subawards involved an antiviral drug discovery project.

30. These terminations will result in the loss of $2.4 million in research money to OHSU.

31. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my 25 years working at OHSU, I have not seen this language previously used to cancel grants.

32. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, OHSU had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was OHSU provided with any updated "agency priorities" with which its research must align.

Comparisons Across Administrations

33. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

34. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo and renewals have been delayed.

35. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations.

36. These delays have forced us to implement bridge funding for dozens of faculty, drawing from limited discretionary resources. As of April 1, 2025, OHSU has implemented bridge funding of approximately $1 million during the FY25 fiscal year. This prevents the use of these funds for any other purpose, including other planned improvements to our programs and research.

37. We have paused start-up funding for new hires whose research programs depend on timely NIH awards. This includes several new hires we had provided offer letters to and for whom OHSU had taken steps to prepare for their arrival.

Admissions, Training and Workforce Disruptions

38. OHSU uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

39. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

40. We have international postdocs whose visa status is now at risk due to pending NIH awards that were expected to renew this spring.

41. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the

research capabilities of OHSU, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

42. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

43. Several proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

44. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

45. The delays have disrupted ongoing research, as well as setting back OHSU for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the interim funding measures being taken by OHSU to keep certain research going. OHSU has had to consider which of these valuable programs to continue with these limited funds.

46. Some of these studies involve the use of animal test subjects, all of which would need to be euthanized due to loss of funding.

47. Some of these studies had the potential to achieve breakthroughs in many different disciplines, which would have advanced public health, and which will now not occur.

48. Delays have also disrupted community services, student opportunities, and public programs.

49. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

50. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Signed by:
Peter Barr-Gillespie
455E7C4804C8478...

Peter G. Barr-Gillespie, Ph.D,

Date: 4/3/2025

EXHIBIT A

Kellie Guentert

Subject: FW: Grant Termination Notification
Attachments: 1015566-002_Roberts_3R01DK122843-05S1-APRC01318_50224 (2).pdf

Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Monday, March 24, 2025 12:52 PM
Jason Jaworski <jaworski@ohsu.edu>
[EXTERNAL] Grant Termination Notification

National Institutes of Health
Office of Extramural Research

3/24/2025

Jaworski, Jason N
Oregon Health & Science University
jaworski@ohsu.edu

Dear Jaworski, Jason N:

Effective with the date of this letter, funding for Project Number 3R01DK122843-05S1 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 7/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Dee Doherty, Chief Grants Management Officer, NIDDK
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 35

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF SUSAN PHILIP

I, Susan Philip, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the following information is true and correct:

1. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the San Francisco Department of Public Health (SFDPH) staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am physician board certified in both Internal Medicine and Infectious Diseases, the Health Officer for the City and County of San Francisco (the City), and the Director of the Population Health Division (PHD) of the SFDPH. SFDPH is a City department whose mission is to protect and promote the health of all San Franciscans.

4. I received my M.D. from Washington University in St. Louis and trained as a resident in Internal Medicine at the University of Chicago. I also have an MPH from the Harvard

School of Public Health, after which I completed a fellowship in Infectious Diseases at the University of California, San Francisco (UCSF). I am an Assistant Clinical Professor of Medicine in the Division of Infectious Diseases at UCSF, and have previously been an HIV primary care provider at San Francisco City Clinic

5. As the City's Health Officer, I am charged under California law with taking any preventative measure that may be necessary to protect and preserve the public health from any public health hazard during a 'state of war emergency,' 'state of emergency,' or 'local emergency.' I am also responsible for issuing orders to other governmental entities within my jurisdiction to take any action that I deem necessary to control the spread of the communicable disease.

6. As Director of PHD, I oversee 16 branches within SFDPH that promote and protect public health through mandated public health functions including disease surveillance, environmental safety, health promotion and chronic disease prevention, preparation and response to public health emergencies, and monitoring of emerging and ongoing infections and diseases.

7. In addition, I closely supervise and monitor the Research, Learning, and Development Group, which is comprised of three branches: Bridge HIV, Center for Public Health Research (CPHR), and Center for Learning and Innovation. Bridge HIV and CPHR are the only two research branches of SFDPH, where experts conduct nationally and internationally recognized research in multiple public health fields, including HIV and substance use.

8. SFDPH's research program has been conducting cutting-edge research focused on the practical population health needs of its communities for over 30 years. It is very unusual to have a county public health program that performs its own research, let alone a program that consistently wins prestigious competitive grants from the National Institutes of Health (NIH).

San Francisco's discoveries provide benefits nationwide. For example, SFDPH clinics were the first to recommend doxycycline post-exposure prophylaxis (doxyPEP) to reduce transmission of STIs. The City has seen population-level decreases in syphilis and chlamydia infections and planned further research to refine and study doxyPEP treatment.

9. I am providing this declaration to explain the impacts of delay and/or cancellation of City grants by the NIH.

Typical Timeline and Processes for NIH Grant Awards

10. Researchers from Bridge HIV and the Center for Public Health Research submit grant applications and track applications and awards as part of the Population Health Division.

11. Based on my 20 years of work at SFDPH, I have an understanding of the NIH grant process.

12. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

13. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some ICs publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to

balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

14. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to recommend a grant for funding is made. After the advisory council meets, the relevant institute's Director typically approves the recommended grants, and a Notice of Award is promptly issued confirming the grant will be funded.

15. The process for competitive renewals is very similar, except that a grant that has been funded in the past is even more likely to be renewed.

16. The budget process at SFDPH relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within months of submission.

17. Once a grant receives a score, SFDPH is able to consider whether to include the funding coming from that grant as part of its budget for the coming year

Delays and Irregularities in the Processing of NIH Grant Applications

18. Since late January 2025, the City has seen an unusual number of delays in the processing of NIH grant applications. PHD is the subrecipient of incoming grants that have been significantly delayed. PHD anticipated receiving a Notice of Award (NOA) for the following grants: the Bridge Clinic: Optimizing Injectable PrEP Delivery for Transgender and Non-Binary People; Project Chill: Randomized controlled trial of as-needed olanzapine for self-management of methamphetamine-associated psychosis; the Camino Study: Evaluating a pilot legal intervention to reduce HIV risk among high risk Latina/o/x sexual/gender minorities; and the BEYOND Study.

19. PHD had previously been informed that it would receive these funds as long PHD had "satisfactory programmatic progress" and there was an "availability of funds." On information and belief, I understand these conditions have been met for each of the above-mentioned grants.

20. PHD has not received formal notice of changes for these grants, and has only been advised that the proposals are "paused" or "under review."

21. As of April 2, 2025, PHD is awaiting roughly $3 million in grants from NIH.

Terminations of NIH Grants

22. Since late January 2025, NIH has terminated twelve grants that funded PHD research.

23. The notices of termination received as of April 2, 2025 are attached hereto as Exhibits A-I.

24. These terminations will result in the loss of roughly $1,204,788.00 in research money to SFDPH.

25. The termination notices for these grants have provided very little explanation as to the reason for the terminations, noting only that the research no longer "effectuates agency priorities." In my 20 years of working at SFDPH, I have not seen this language previously used to cancel grants.

26. The termination notices also state that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, SFDPH had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was SFDPH provided with any updated "agency priorities" with which its research must align.

27. The terminated grants include the following: Tailoring Delivery of LongActing PrEP for Cisgender MSM who use methamphetamine; MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women; PrEP-3D: An Integrated Pharmacy Digital Diary and Delivery Strategy to Increase PrEP Use Among MSM; SHINE: Strong: Building The pipeline of HIV behavioral scientists with expertise in trans pop health; One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States; T'Cher, Take Charge: PrEP for trans women in the Deep South; DoxyPEP Impact Study; Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) HIV and Pregnancy Prevention in Youth (HAPPY); ATN Operations and Collaborations Center; ATN Scientific Leadership Center; Short Trainings on Methods for Recruiting, Sampling, and Counting Hard-to-Reach Populations: The H2R Training Program.

Comparisons Across Administrations

28. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

29. Renewals were routine and predictable. Terminations were exceedingly rare and followed due process.

30. This year, even long-standing, high-performing programs are in limbo. The current approach is without precedent in our experience.

Concerns About FY25 Funds Being Obligated

31. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

32. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

33. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

34. The City and County of San Francisco is severely harmed by NIH's funding delays and terminations. The City's capacity to create research-informed public health programs is diminished; one-half of the City's public health research projects has been terminated or delayed by NIH. For example, all of SFDPH's research comes from Bridge HIV and the Center for Public Health Research at SFDPH. Over fifty percent of Bridge HIV's research projects have been terminated by NIH. And the Center for Public Health Research had 12 ongoing research projects, but only 4 have not been impacted by the NIH's terminations, delays, and failure to review and renew grants.

35. SFDPH's grants are aimed at stopping the spread of communicable diseases including HIV. NIH terminated almost the entirety of SFDPH's research into PrEP, a medication that significantly reduces a person's risk of contracting HIV. SFDPH's PrEP research is meant to support San Francisco "Getting to Zero San Francisco" initiative, which aims to achieve zero new HIV infections, zero HIV-related deaths, and zero HIV stigma by 2025.

36. NIH terminated or delayed SFDPH research intended to engage with vulnerable populations who have a higher rate of contracting and spreading communicable diseases, such as

the transgender community and drug users. Over $800,000 has been lost towards this goal, further impacting the City's ability to reach its "Getting to Zero San Francisco" goal.

37. NIH's terminations and delays have also impacted SFDPH's ability to maintain its workforce. SFDPH will lose vital researchers, analysts, and staff if it cannot replace the funding NIH terminated. SFDPH has also had to terminate recruitment efforts due to lack of funding.

38. NIH's terminations and delays have also impacted SFDPH's capacity to prevent the spread of other communicable diseases, including bacterial STIs. Specifically, NIH terminated funding for the Doxy-PEP Impact Study (DoxyImpact), a longitudinal study to assess the use of post-exposure doxycycline in preventing bacterial STI transmission at study sites in five U.S. cities.

39. In many cases, there is no way to recover the lost time, research continuity, or training value once the research is disrupted.

40. The delays have disrupted ongoing research, and will inhibit SFDPH's capacity to conduct research going forward. Funding gaps have forced researchers to abandon studies or lose key personnel.

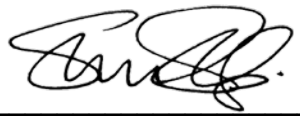
Conclusion

41. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

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//
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I declare under penalty of perjury under the laws of the United States that, to the best of my knowledge, the foregoing is true and correct.

Executed on April 2, 2025, at San Francisco, California



Susan Philip, MD, MPH

EXHIBIT A

FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 1
PTE/Prime Award No.: 7R21DA058575-02
Subaward No: AH1058/PH1058A CCSF DPH

Pass-Through Entity (PTE)		Subrecipient
Harvard Pilgrim Health Care, Inc., on behalf of itself and Harvard Pilgrim Health Care Institute, LLC	Entity Name	City and County of San Francisco Department of Public Health
research_admin@hphci.harvard.edu	Contact Email	albert.liu@sfdph.org
Vanessa McMahan, PhD	Principal Investigator	Albert Liu

Project Title: Tailoring Delivery of LongActing PrEP for Cisgender (MSM) Who Use Methamphetamine

Cumulative Budget Period(s) (Agreement Start Date) Start Date: 09/01/2024 (End Date of Latest Budget Period) End Date: 03/21/2025	Amount Funded This Action	Total Amount of Funds Obligated to Date
	$ 0.00	$ 23,393.00

Subrecipient Cost Share ☐ | Subject to FFATA ■ | Subrecipient UEI (Unique Entity Identifier - May leave blank if unchanged from prior Agreement): DCTNHRGU1K75

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Subaward Agreement as follows:

☐ **Additional Budget Period**

☐ **No Cost Extension**

☐ **Additional Funding**

☐ **Deobligation**

Carryover is

☐ **Carryover Authorized**

☐ **Detailed Budget/Scope of Work/Notice of Award Attached** (Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")

■ **Other (See Below)**

Notice of early termination effective 03/21/2025

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Date		Date	
Name	Cary Williams	Name	
Title	Director, Office of Sponsored Programs	Title	

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Notice of Award
FAIN# R21DA058575
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Vanessa McMahan

vanessa_mcmahan@hphci.harvard.edu
617-864-4260

8. Authorized Official
Cary Williams
research.admin@hphci.harvard.edu
617-867-4958

Federal Agency Information

9. Awarding Agency Contact Information
Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE
pfleming@mail.nih.gov
301-480-1159

10. Program Official Contact Information
Richard A Jenkins
Health Scientist Administrator
NATIONAL INSTITUTE ON DRUG ABUSE
jenkinsri@mail.nih.gov
301-443-6504

Federal Award Information

11. Award Number
7R21DA058575-02

12. Unique Federal Award Identification Number (FAIN)
R21DA058575

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Tailoring Delivery of LongActing PrEP for Cisgender (MSM) who Use Methamphetamine

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction Research Programs

17. Award Action Type
Change of Recipient Organization (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$220,370
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$220,370
26. Project Period Start Date 09/01/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$220,370

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Pamela G. Fleming

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 7R21DA058575-02 REVISED

Principal Investigator(s):
Vanessa McMahan

Award e-mailed to: research_admin@hphci.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R21DA058575. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$28,998

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Fringe Benefits	$8,641
Personnel Costs (Subtotal)	$37,639
Travel	$4,000
Subawards/Consortium/Contractual Costs	$99,331
Publication Costs	$3,000
Federal Direct Costs	$143,970
Federal F&A Costs	$76,400
Approved Budget	$220,370
Total Amount of Federal Funds Authorized (Federal Share)	$220,370
TOTAL FEDERAL AWARD AMOUNT	$220,370
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$220,370	$220,370

Fiscal Information:
Payment System Identifier: 1042452600A1
Document Number: RDA058575B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
DA	8472628	$220,370

NIH Administrative Data:
PCC: CV/RJP / **OC**: 41025 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:10:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 7R21DA058575-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 7R21DA058575-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than

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the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21DA058575. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DA SPECIFIC AWARD CONDITIONS – 7R21DA058575-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION #1 - TERMINATION

It is the policy of NIH not to further prioritize research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination since race and other protected characteristics, which harms the health of Americans.
Therefore, this project is terminated.

The Harvard Pilgrim Health Care, Inc. may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly closeout process, will need to submit the necessary closeout documents (i.e. Final Research Performance Program Report (F-RPPR), Final Invention Statement (FIS), and the Final Federal Financial Report (FFR)) within 120 days of the end date of this grant to avoid unilateral closeout.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

This revision supersedes Notice of Award (NoA) issued 8/09/2024.

_____

CHANGE OF RECIPIENT
Support for this project was previously funded via 1 R21 DA 058575-01 at Public Health Foundation Enterprises.

CONSORTIUM ACTIVITY
This award includes funds awarded for consortium activities. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS), Section on Consortium Agreements - http://grants.nih.gov/policy/nihgps/index.htm.

The recipient is reminded of the *NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements* as published in the NIH Guide notice NOT-OD-23-182 on September 15, 2023 with an effective date of January 1, 2024. The notice can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html

NOFO REQUIREMENTS
This award is subject to the requirements detailed in PAR-22-109, “Dissemination and Implementation Research in Health (R21 Clinical Trial Optional): posted on 05/10/2022 which are incorporated by reference as terms and conditions of this award.

The NOFO is available here: PAR-22-109: Dissemination and Implementation Research in Health (R21 Clinical Trial Optional) (nih.gov)

NIDA TERMS
In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding.

SPREADSHEET SUMMARY
AWARD NUMBER: 7R21DA058575-02 REVISED

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INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 2
Salaries and Wages	$28,998
Fringe Benefits	$8,641
Personnel Costs (Subtotal)	$37,639
Travel	$4,000
Subawards/Consortium/Contractual Costs	$99,331
Publication Costs	$3,000
TOTAL FEDERAL DC	$143,970
TOTAL FEDERAL F&A	$76,400
TOTAL COST	$220,370

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	66%
F&A Cost Base 1	$115,757
F&A Costs 1	$76,400

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EXHIBIT B

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

March 26, 2025

San Francisco Department of Public Health
101 Grove Street, Room 410
San Francisco, CA 94102
Attention: Sajid Shaikh
Phone: (415) 554-2778
Email: Sajid.shaikh@sfdph.org

Subject: NIH Termination Letter: Notification of Termination

We are writing to formally notify you that Heluna Health received a termination letter from the National institutes of Health (NIH) for Project Number 1R34MH132405-01 (HH Project Number: 1067.0101) to cease all activities associated with this project effective March 21, 2025.

Costs resulting from financial obligations incurred after termination are not allowable. To comply with this termination, Heluna Health is initiating the closeout requirements for this project.

To facilitate the closeout process, as listed in your attached Amendment #1 please submit your final invoice for cost incurred no later than March 21, 2025, along with required back up documentation as stated in the attached Amendment #1, by April 11, 2025.

Amendment #1 is attached. Please return the signed amendment no later than March 31, 2025.

If you have any questions, please contact Adam Abate, Senior Contract and Grant Manager, at AAbate@HelunaHealth.org

Sincerely,

DocuSigned by:
Rochelle McLaurin
11FA7C5B062940D...

Rochelle McLaurin
Director, Contracts and Grants Management

Attachment:

Amendment Number 1:

CC:

Susan Buchbinder

Peter Dale

Rochelle McLaurin

Adam Abate

Docusign Envelope ID: 878C1F25-FF3E-40DB-90B5-ACC2E062A96E

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969
13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
Phone: 800.201.7320 | Fax: 562.205.2453 | www.helunahealth.org

SUBCONTRACT/SUBRECIPIENT AMENDMENT 1

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

1067.0101 MYPREP PLUS

This [Subcontract/Subaward] Agreement (this "Agreement") is amended as follows:

Pursuant to Section 6 Term and Termination, Clause C Termination for cause, Part 2 of the Agreement, "if either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services," effective March 21, 2025, funding for Project Number 1R34MH132405-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grant Policy Statement, and 2 C.F.R. § 200.340 (a)(2). Heluna Health along with City and County of San Francisco will be terminating the Subcontract for the project titled "MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women". City and County of San Francisco should cease services as of the effective date of termination March 21, 2025, and cancel any outstanding obligations and not incur any additional obligations.

TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from September 7, 2023, and is amended to end on March 21, 2025.

EXHIBIT D – FORM OF INVOICE

The final invoice is due April 11, 2025 via email to Tyler Norgord at TNorgord@helunahealth.org with a copy to Adam Abate AAbate@helunahealth.org.

All other terms and conditions of the original Subcontract/Subaward Agreement remain in full force and effect.

Signatures acknowledging this amendment are below.

HELUNA HEALTH

By: DocuSigned by: Rochelle McLaurin 11FA7C5B062940D... _____ Date: 3/26/2025

Rochelle McLaurin
Director, Contract and Grant Management

THE CITY AND COUNTY OF SAN FRANCISCO

By: _____ Date: _____

Grant Colfax, MD
Director of Health
Department of Public Health

Approved as to Form

David Chiu
City Attorney

By: _____ Date: _____

Henry Lifton
Deputy City Attorney

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
Phone: 800.201.7320 | Fax: 562.205.2453 | www.helunahealth.org

[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

This [Subcontract/Subaward] Agreement (this "Agreement") is made and entered into as of 4/19/2024 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., DBA Heluna Health, a 501(c)(3) California nonprofit corporation (hereinafter referred to as "HELUNA HEALTH"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee."

RECITALS

A. HELUNA HEALTH has been granted an award by Department of Health and Human Services (the "Funding Agency"); under contract number 1R34MH132405-01; Federal Award Identification Number (FAIN) R34MH132405; and Catalog of Federal Domestic Assistance (CFDA) number 93.242 under which HELUNA HEALTH and its subcontractors and subawardees will collaborate on the program.

B. Subcontractor/Subawardee has expertise in the necessary area(s) which their expertise can assist HELUNA HEALTH to perform its obligations under the Funding Award Agreement; and

C. HELUNA HEALTH desires to engage the services of Subcontractor/Subawardee to assist HELUNA HEALTH in the performance of certain of its obligations under the Funding Award Agreement as set forth herein.

D. The Parties understand and agree that any funding amount above $1,000,000, that constitutes revenue to the City requires formal approval by the San Francisco Board of Supervisors acting in its sole discretion under San Francisco Charter Section 9.118.

AGREEMENT

1. IDENTITIES OF PARTIES

SUBCONTRACTOR/SUBAWARDEE:

Legal Name of Subcontractor/Subawardee: City and County of San Francisco
DBA of Subcontractor/Subawardee: San Francisco Department of Public Health
Type of Entity: [ ] Sole Proprietorship; [ ] Partnership; [ ] Corporation;
[ ] Limited Liability Company; [X] Government

State of Organization (if an entity): California
Address: 101 Grove Street, Room 402
City/State/Zip: San Francisco, CA 94102
Business Telephone: (415) 554-2778
Social Security or Employer Identification Number: 94-6000417
License Number and Expiration Date, if any: N/A
Email Address: Sajid.shaikh@sfdph.org

Name of Principal Investigator/Project Coordinator: Susan Buchbinder
Phone Number of Principal Investigator/Project Coordinator: (415) 476-2300

Is Subcontractor/Subawardee required to file a Single Audit with the Federal Government? (Required for parties who receive Federal funds in the aggregate amount of $750,000 or more):
[X] Yes [ ] No

If yes, has Subcontractor/Subawardee filed the required Single Audit? [X] Yes [ ] No
(If yes, submit copy to HELUNA HEALTH prior to signing this Agreement)

HELUNA HEALTH:

Heluna Health
Address and Phone #: 13300 Crossroads Parkway North, Suite 450, City of Industry, CA, 91746-3505; (562) 699-7320
Program Name: MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women
Program/CID #: 1067.0101
Project Director Name: Susan Buchbinder
Project Director Phone #: (415) 476-2300
Project Director Email Address: susan.buchbinder@sfdph.org
Contracts Manager Name: Adam Abate
Contracts Manager Email Address: AAbate@helunahealth.org

2. SCOPE OF SERVICES

(a) Services. Subcontractor/Subawardee shall perform the services, duties and obligations set forth in the Statement of Work ("SOW") attached as Exhibit A hereto, which is made a part hereof and incorporated herein by reference (the "Services"). The Services relate Exhibit C, if attached hereto. Subcontractor/Subawardee shall perform the Services in accordance with the specifications, timetables and requirements set forth in the SOW and this Agreement. HELUNA HEALTH may, in its discretion, provide to Subcontractor/Subawardee a copy of the Funding Award Agreement or the relevant sections thereof. If Subcontractor/Subawardee is provided with a copy of the Funding Award Agreement or the relevant sections thereof, Subcontractor/Subawardee shall carefully review them and shall

perform the Services in accordance with the specifications, timetables and requirements set forth therein.

(b) Location(s) of Services. Subcontractor/Subawardee shall perform the Services at the following location(s):

101 Grove Street, Room 402
San Francisco, CA 94102

(c) Subcontractor/Subawardee Principal Investigator/Project Coordinator. Subcontractor/Subawardee shall appoint the Principal Investigator/Project Coordinator (the "PI") identified above to be primary point of contact with HELUNA HEALTH with respect to the Services and to have primary responsibility within Subcontractor's/Subawardee's organization for the performance of the (technical or programmatic) aspects of the Services. Subcontractor/Subawardee shall not replace or reassign the PI without HELUNA HEALTH's prior written approval.

(d) HELUNA HEALTH Project Director. The HELUNA HEALTH Project Director identified above shall be primarily responsible on behalf of HELUNA HEALTH for the overall direction of the Services, including review and approval of Subcontractor's/Subawardee's performance of the Services. HELUNA HEALTH will notify Subcontractor/Subawardee if HELUNA HEALTH replaces or reassigns such Project Director.

(e) Performance Reporting. If requested by HELUNA HEALTH or the Funding Agency, Subcontractor/Subawardee shall submit a final technical or performance report, annual performance report, and quarterly performance reports. The final report shall be due 30 days after expiration or termination of this Agreement; annual reports and quarterly reports shall be due 30 days after the reporting period. Subcontractor/Subawardee shall also provide any other reports as may be requested by HELUNA HEALTH. Performance reports shall include a comparison of actual accomplishments with goals and objectives established for the period, findings of the PI, or both, as requested by HELUNA HEALTH. Where possible, quantitative output data should be related to cost data for computation of unit costs. Other pertinent information will include, when appropriate, the reasons why established goals were not met and an analysis. Subcontractor/Subawardee shall immediately notify HELUNA HEALTH of developments that have a significant impact on the performance of the Services hereunder and of any problems, delays, or adverse conditions that materially impair its ability to meet the objectives of the Services, including providing a statement of the action taken or contemplated and any assistance needed to resolve the situation.

3. COMPLIANCE WITH FUNDINGAWARD AGREEMENT AND LAWS AND REGULATIONS; FLOW DOWN PROVISIONS

(a) Compliance with Funding Contract. Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of

the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached hereto as Exhibit C, that are applicable to Subcontractor/Subawardee and Subcontractor's/Subawardee's activities.

(b) Flow Down Provisions. Without limiting the generality of Section 3(a) above, Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the flow-down provisions of the Funding Award Agreement applicable to Subcontractor/Subawardee, if attached as Exhibit C (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions, if attached as Exhibit C, and is able to comply with all of the Flow Down Provisions. In the event that the requirements set forth in the Flow Down Provisions are greater than the requirements set forth in this Agreement, or in the event of any conflict between the provisions of this Agreement and the Flow Down Provisions, the Flow Down Provisions shall control and Subcontractor/Subawardee shall comply with the requirements set forth in the Flow Down Provisions in accordance with Section 2(a).

(c) Laws and Regulations. Subcontractor/Subawardee shall also comply with all state and federal statutes and regulations applicable to Subcontractor/Subawardee, the Services or the Funding Award Agreement, in performing its obligations under this Agreement. Without limiting the generality of the foregoing, Subcontractor shall:

(i) unless exempt, comply with the requirements under 45 CFR Part 74, and the Public Health Service Grants Policy Statement;

(ii) unless exempt, comply with Executive Order 11246 entitled "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemental in Dept. of Labor regulations (41 CFR Part 60);

(iii) comply with (and not violate) all statutes, laws, rules and regulations relating to non- discrimination against any employees or applicants for employment, including, without limitation, Title VII of the Civil Rights Act of 1964, The Americans with Disabilities Act Amendments Act of 2008, and the California Fair Employment and Housing Act (if Subcontractor/Subawardee is located within California), and shall take affirmative action to ensure that all employment related decisions are made in conformance with all such statutes, laws, rules and regulations; and

(iv) unless it is exempt from doing so, comply with 45 CFR Part 76, Appendix B-Certification Regarding Debarment, Suspension, and Ineligibility, Voluntary Exclusion-Lower Tier Covered Transactions.

(d) HIPAA Business Associate Agreement. If the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is applicable to the Services, Subcontractor/Subawardee shall execute and deliver HELUNA HEALTH's standard Business Associate Agreement as required by HIPAA.

(e) Lower-tier Subcontractors/Subawardees. Subcontractor/Subawardee shall incorporate all of the terms and conditions of this Agreement into all lower-tier subcontracts that Subcontractor/Subawardee may enter into in connection with this Agreement, and shall ensure that all such lower-tier subcontractors/subawardees and their personnel comply with all of the requirements of this Agreement applicable to Subcontractor/Subawardee, and all of the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached as Exhibit C, including the Flow Down Provisions, that are applicable to such lower-tier subcontractors'/subawardees' activities.

4. PAYMENT FOR SERVICES

(a) Budget. The total compensation and reimbursements payable to Subcontractor/Subawardee hereunder shall be as set forth in the detailed budget for the Services attached hereto as Exhibit B (the "Budget"), which is made a part hereof and incorporated herein by reference. The maximum amount payable to Subcontractor/Subawardee hereunder shall not exceed the maximum amount set forth in the Budget.

(b) Must Stay Within Budget Time Periods. Subcontractor/Subawardee shall be compensated only for Services actually performed by Subcontractor/Subawardee and within the appropriate time period set forth in the Budget.

(c) Approval of Services by HELUNA HEALTH. All Services must be completed to the satisfaction of HELUNA HEALTH in order to be entitled to payment hereunder.

(d) Funds Available to HELUNA HEALTH. HELUNA HEALTH shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to HELUNA HEALTH under the Funding Award Agreement.

(e) Billing of Expenses and Costs. All expenses and costs shall be billed in accordance with the approved budget. Expenses incurred after the expiration or termination of this Agreement shall be disallowed. Subcontractor/Subawardee shall submit its final invoice no later than 30 days after the date of expiration of the term or termination of this Agreement.

(f) Budget Modifications. The Budget may be modified only by written agreement of HELUNA HEALTH and Subcontractor/Subawardee and the prior written approval of the Funding Agency.

5. INVOICING PROCEDURES

(a) Approval by Funding Agency. If required under the Funding Award Agreement, attached hereto as Exhibit C, Subcontractor/Subawardee must first submit all timesheets and invoices to the Funding Agency for approval by the Funding Agency. After the Funding Agency

has approved a timesheet and invoice submitted by Subcontractor/Subawardee, Subcontractor/Subawardee shall submit the same to HELUNA HEALTH.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the HELUNA HEALTH Project Director at the address set forth in Section 1 above.

(c) Invoicing Period. All invoices shall be submitted not more frequently than monthly, in arrears and must be submitted to HELUNA HEALTH within 30 days after the end of the applicable month or within 15 days after approval by the Funding Agency (if applicable), whichever is later. All final invoices must be received within 30 days of the expiration or termination of this Agreement or within such earlier time period as HELUNA HEALTH may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in HELUNA HEALTH's discretion) all rights to payment under such invoices.

(d) Formatting and Requirements of Invoices. All invoices shall be submitted in the form attached hereto as Exhibit D, as it may be modified by HELUNA HEALTH from time to time.

6. TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from September 7, 2023 to September 6, 2025 (the "Term").

(b) Termination Without Cause. Reserved.

(c) Termination for Cause. With reasonable cause, either party may terminate this Agreement effective immediately upon the giving of written notice of termination for cause. Reasonable cause shall include:

i. A material violation or breach of this Agreement by the other party which is not cured within 15 days after written notice from the terminating party;

ii. Any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; or

iii. If either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services.

(d) Termination for Lack of Funding. HELUNA HEALTH may terminate this Agreement if for any reason the funding available under the Funding Award Agreement is withdrawn, limited, or impaired.

(e) Cessation Upon Termination. On the effective date of termination, Subcontractor/Subawardee shall cease all further Services under this Agreement, and Subcontractor/Subawardee shall cancel as many outstanding obligations as possible and not incur any additional obligations.

(f) Payment After Termination. Subject to the terms and conditions set forth in this Agreement, upon termination of this Agreement, provided, that HELUNA HEALTH has received the corresponding funds from the Funding Agency under the Funding Award Agreement , HELUNA HEALTH shall pay for any reasonable non-cancellable obligations properly incurred by Subcontractor/Subawardee under this Agreement and in accordance with the Budget prior to termination, and shall pay any amounts due to Subcontractor/Subawardee and properly invoiced under this Agreement for Services performed prior to termination; provided, that if HELUNA HEALTH has terminated this Agreement for reasonable cause under Section 6(c) above, then HELUNA HEALTH shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by HELUNA HEALTH as a result of such violation or breach.

(g) Return of Materials. Reserved.

(h) Surviving Provisions. The provisions of Sections 7 through 16, and any other sections that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive.

7. REPRESENTATIONS AND WARRANTIES. Subcontractor/Subawardee represents, warrants and covenants to HELUNA HEALTH as follows:

(a) Licenses and Permits. Subcontractor/Subawardee maintains and shall maintain during all relevant times under this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Subcontractor/Subawardee as a business operator.

(b) Qualifications and Performance. Subcontractor/Subawardee (i) has the experience and skill to perform the Services hereunder, (ii) shall perform the Services in a good and workman like manner and in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices, and (iii) is adequately financed to meet any financial obligation it may be required to incur hereunder.

(c) Not Debarred. Neither Subcontractor/Subawardee nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended,

proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

8. INDEPENDENT CONTRACTOR STATUS

(a) Independent Contractor. Nothing in this Agreement is intended to place the parties in the relationship of employer-employee, partners, joint venturors, or in anything other than an independent contractor relationship. It is the parties' intention that Subcontractor/Subawardee shall be an independent contractor and not HELUNA HEALTH's employee or agent, and in conformity therewith, that Subcontractor/Subawardee shall retain sole and absolute discretion and judgment in the manner and means of carrying out Subcontractor/Subawardee's Services hereunder. Subcontractor/Subawardee is under the control of HELUNA HEALTH as to the results of Subcontractor/Subawardee's Services only, and not as to the means by which such results are accomplished.

(b) No Power to Bind HELUNA HEALTH. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of HELUNA HEALTH for any purpose whatsoever. Subcontractor/Subawardee is not granted any right or authority to assume or create any obligation or responsibility, or to make any promise or commitment regarding any work, on behalf of or in the name of HELUNA HEALTH or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of HELUNA HEALTH, without the prior written consent from HELUNA HEALTH management. No sales, invoices nor orders for goods or services shall be valid and binding upon HELUNA HEALTH (whether as the provider or the recipient) unless and until accepted by HELUNA HEALTH, at its sole and absolute discretion, through its established channels. HELUNA HEALTH shall not be liable for any obligation incurred by Subcontractor/Subawardee.

(c) No Withholding. Except for tax withholdings that are required by law, neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by HELUNA HEALTH on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees or HELUNA HEALTH with respect to the Services performed hereunder for federal or state tax purposes or for any other purposes.

(d) No Employee Benefits. Neither Subcontractor/Subawardee nor its personnel shall be eligible for, and shall not participate in, any of HELUNA HEALTH's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by HELUNA HEALTH concerning Subcontractor/Subawardee or Subcontractor's/Subawardee's personnel. Subcontractor/Subawardee shall comply with all workers' compensation laws concerning Subcontractor/Subawardee and its personnel.

(f) Taxes. Subcontractor/Subawardee understands that Subcontractor/Subawardee is responsible to pay, according to law, Subcontractor's/Subawardee's income taxes. If Subcontractor/Subawardee is not an entity, Subcontractor/Subawardee further understands that Subcontractor/Subawardee may be liable for self-employment (social security) tax, to be paid by Subcontractor/Subawardee according to law. Subcontractor/Subawardee shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Subcontractor/Subawardee or its employees as a result of or in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee represents and warrants and covenants that it shall report all income earned as a result of this Agreement and pay all federal, state and local income and self-employment taxes and other assessments required to be paid under applicable law. Subcontractor/Subawardee agrees to defend, indemnify and hold HELUNA HEALTH harmless from any and all claims made by federal, state and local taxing authorities on account of Subcontractor's/Subawardee's failure to pay any such federal, state or local income and self-employment taxes or other assessments due as a result of Subcontractor's/Subawardee 's Services hereunder.

(g) Sub-Tier Subcontractors/Subawardees. Subcontractor/Subawardee shall have control over the manner and means of Subcontractor/Subawardee's performance under this Agreement. However, HELUNA HEALTH is engaging Subcontractor/Subawardee for Subcontractor's/Subawardee's unique skills, knowledge, abilities and other attributes. Any lower-tier subcontractors/subawardees who are approved by HELUNA HEALTH must execute all agreements and documents required by HELUNA HEALTH prior to performing any work. Subcontractor/Subawardee shall ensure that all lower-tier subcontractors/subawardees comply with all of the terms and provisions of this Agreement and shall be responsible and liable for all acts and omissions of all lower-tier subcontractors/subawardees as if they were the acts or omissions of Subcontractor/Subawardee.

9. OWNERSHIP OF WORK PRODUCT

(a) Ownership of Work Product. Subcontractor/Subawardee owns all work product developed under this Agreement.

(b) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(c) No Harmful Code. With respect to the website and any computer programs or software code ("Software") included in the Services hereunder, Subcontractor/Subawardee represents and warrants that: (i) the Software and its media shall contain no computer instructions or inappropriate functions whose purpose or result is to disrupt, damage or interfere with HELUNA HEALTH's or its affiliates' or their customers' use of or access to the Software or any of their data, programs or computer or telecommunications facilities and (ii)

unless expressly authorized in writing by HELUNA HEALTH, such Software shall not contain any mechanism which electronically notifies Subcontractor/Subawardee of any fact or event, nor contain any key, node lock, time-out, logic bomb or other function, implemented by any means, which may restrict HELUNA HEALTH's or its affiliates' or customers' use of or access to the Software or any other programs, data or equipment.

10. PUBLICATIONS

(a) Right to Publish Works. Subcontractor/Subawardee may, with HELUNA HEALTH's and the Funding Agency's prior written consent, publish articles written by Subcontractor/Subawardee in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee shall submit all such articles for review by HELUNA HEALTH and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by HELUNA HEALTH and the Funding Agency as described above, Subcontractor/Subawardee shall place an acknowledgment of federal government support, and shall include a disclaimer, as appropriate, as follows: "The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of Heluna Health. or **[Name of Funding Agency]**".

(c) Use of HELUNA HEALTH's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner HELUNA HEALTH's name, logo or trademarks without HELUNA HEALTH's prior written consent. Subcontractor/Subawardee shall not use in any manner the Funding Agency's name, logo or trademarks without the Funding Agency's prior written consent.

11. INDEMNIFICATION

HELUNA HEALTH hereby agrees to indemnify, hold harmless and defend Subcontractor/Subawardee, its officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of HELUNA HEALTH, (ii) HELUNA HEALTH's violation of any federal, state or local law or regulation or (iii) the breach by HELUNA HEALTH of any its representations, warranties or agreements under this Agreement.

12. INSURANCE

Subcontractor/Subawardee shall, unless otherwise agreed in writing by HELUNA HEALTH, maintain: (i) Workers' Compensation insurance, (ii) Professional Liability Insurance and Commercial General Liability Insurance (including broad form contractual and automobile liability coverage), with minimum limits of ONE MILLION DOLLARS ($1,000,000) combined single

limit per occurrence, and (iii) Automobile Liability on each automobile owned by him/her/it or his/her/its agents, subcontractors/subawardees or employees, which is used at any time to carry out Subcontractor's/Subawardee's duties hereunder, with minimum limits of $100,000 per person and $300,000 per occurrence for bodily injury. If higher or additional coverages are required under the Flow Down Provisions, attached as Exhibit C, Subcontractor/Subawardee shall procure such coverages. A program of self-insurance is acceptable.

13. CONFIDENTIALITY

(a) Sunshine Ordinance. HELUNA HEALTH acknowledges that this Agreement and all records related to its formation, and the performance of Services, and HELUNA HEALTH's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

(b) Confidential Information. Confidential Information includes, but is not limited to, the identity of actual and potential clients of HELUNA HEALTH, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; Subcontractor/Subawardee shall not disclose in any manner whatsoever any of the aforesaid Confidential Information, directly or indirectly, or use it in any way whatsoever, either during this Agreement or at any time thereafter, except as required in the course of Subcontractor's/Subawardee's work with HELUNA HEALTH or except as otherwise provided in this Agreement or permitted by law. Further, Subcontractor/Subawardee shall develop and maintain procedures and take other reasonable steps in furtherance of HELUNA HEALTH's desire to maintain the confidentiality of its Confidential Information.

(c) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement, if attached as Exhibit C.

14. RECORD RETENTION AND ACCESS TO RECORDS

Subcontractor/Subawardee shall grant to HELUNA HEALTH, the Funding Agency and the U.S. Comptroller General and their respective authorized representatives upon demand, access to any books, documents, papers and records of Subcontractor/Subawardee relating to this Agreement or the Services for audit, examination, excerpt and transcription. Subcontractor/Subawardee shall retain all such records for seven (7) years (or longer if required under HELUNA HEALTH's record retention policy, under the Funding Award Agreement or by law, including under Circular A-110, Subpart C, Post-Award Requirements and FAR Subpart 4.7 Contractor Records Retention - 4.703 Policy) after final payment is made under this Agreement and all pending matters are closed, unless extended by an audit, litigation, or other action involving the records, whichever is later.

15. GENERAL TERMS

(a) Amendments. Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

(b) Governing Law; Venue. This Agreement shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California with venue in San Francisco.

(c) Equitable Relief. In light of the irreparable harm to HELUNA HEALTH that a breach by Subcontractor/Subawardee of Sections 9, 10, 13 and 14 of this Agreement would cause, in addition to other remedies set forth in this Agreement and other relief for violations of this Agreement, HELUNA HEALTH shall be entitled to enjoin Subcontractor/Subawardee from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

(d) Binding Agreement. All terms, conditions and covenants to be observed and performed by the parties hereto shall be applicable to and binding upon their respective agents, employees, heirs, executors, administrators, affiliates, subsidiaries, associates, employees, successors and assigns.

(e) Captions. All captions (section headings) set forth herein are inserted only as a matter of convenience and for reference, and shall not affect the interpretation of this Agreement.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which, when taken together, shall constitute one and the same document.

(g) Additional Documents. The parties hereto each agree that they shall execute and, if appropriate, acknowledge any and all additional and other documents, instruments and writings which may be reasonably requested by the other party in order to fully carry out the intent and purpose of this Agreement.

(h) Entire Agreement. This Agreement, and all documents referred to in it, or incorporated in it, is an integrated document containing and expressing all terms, covenants, conditions, warranties and agreements of the parties relating to the subject matter hereof. No other or prior agreements or understandings, written or oral, pertaining to the same shall be valid or of any force or effect.

(i) Facsimile or Email Transmissions. A facsimile transmission or transmission by Email of the executed signature page of this Agreement shall be accepted as, relied upon as, and deemed to be, an original.

(j) Fair Interpretation. The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arm's length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

(k) No Waiver. No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

(l) Notices. Any notice, demand, consent or other communication required or permitted to be given hereunder shall be made in the English language and shall be so given by personal delivery, by (i) registered or certified (return receipt) or First Class United States Postal Service mail, postage pre-paid, or (ii) recognized overnight national courier service, or (iii) facsimile transmission confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, or (iv) by email confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, addressed to the recipient of such notice at the following address or facsimile number, as the case may be, or any other address or facsimile number or email address provided by a party in the manner described hereinabove:

In the case of HELUNA HEALTH, addressed to:

Heluna Health
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746-3505
Attention: Adam Abate
Facsimile: (562) 692-6950
Email: AAbate@helunahealth.org

In the case of Subcontractor, addressed to:

San Francisco Department of Public Health
1380 Howard Street
San Francisco, CA 94103
Attention: Sajid Shaikh
Facsimile: (415) 503-4710
Email: Sajid.shaikh@sfdph.org

And

San Francisco Department of Public Health
101 Grove Street, Room 410
San Francisco, CA 94102
Attention: Contract Analyst
Facsimile: (415) 554-2555
Email: DPH-ContractsRm410@sfdph.org

Any such notice shall be deemed to have been received by the addressee, and service thereof shall be deemed effective, five (5) days following deposit thereof with the United States Postal Service, or upon actual receipt, whichever first occurs, unless the address for delivery is not within one of the United States or its territories or possessions, in which case service shall be effective seven (7) days following deposit, or upon actual receipt, whichever first occurs.

(m) Remedies Non-Exclusive. Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

(n) Severability. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

(o) Limitation of Liability. EXCEPT FOR A BREACH OF SECTIONS 9 AND 13 ABOVE AND EXCEPT TO THE EXTENT INCLUDED IN A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11 ABOVE, IN NO EVENT SHALL ANY PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, AND WHETHER OR NOT THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

(p) Non-Assignability. None of the parties shall assign, transfer, sell, encumber, hypothecate, alienate or otherwise dispose of this Agreement, or any right, title or interest to or in this Agreement, nor shall a party delegate any duty or obligation to be performed hereunder, without the express written consent of the other party having been first obtained, except that any party may assign this Agreement without the consent of the other party in the case of a reorganization, merger, consolidation, or sale of all or substantially all of its assets so long as the assignee expressly assumes all of the obligations of the assignor under this Agreement. Notwithstanding the foregoing, HELUNA HEALTH may assign this Agreement to an

affiliate of HELUNA HEALTH without the consent of the other party. Any attempt to assign this Agreement other than as permitted above shall be null and void.

(q) Signing Person. The individuals signing this Agreement on behalf of an entity represents and warrants that he/she has authority to bind such entity to this Agreement.

[Signatures follow on next page]

The undersigned have caused this Subcontract/Subaward Agreement to be executed as of the date first set forth above:

HELUNA HEALTH

By: DocuSigned by: Rochelle McLaurin 11FA7C5B062940D... Date: 04/29/2024 | 5:01 PM PDT

Rochelle McLaurin
Chief Program Officer
Director, Contract and Grant Management

THE CITY AND COUNTY OF SAN FRANCISCO

By: DocuSigned by: Naveena Bobba 52BC36E46CB9439... Date: 04/30/2024 | 11:08 AM PDT

Grant Colfax, MD
Director of Health
Department of Public Health

Approved as to Form

David Chiu
City Attorney

By: DocuSigned by: Henry Lifton 6D6CB58424584B1... Date: 04/29/2024 | 10:50 PM PDT

Henry Lifton
Deputy City Attorney

Exhibits

Exhibit A: Scope of Work (SOW)
Exhibit B: Budget
Exhibit C: Flow Down Provisions
Exhibit D: Form of Invoice
Exhibit E: Certificate of Self Insurance

EXHIBIT A
TO SUBCONTRACT/SUBAWARD AGREEMENT

SCOPE OF WORK (SOW)

Susan Buchbinder, MD (Principal Investigator):
As Principal Investigator (PI) of this proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, protecting participant safety, and data analysis and publication of results.

Albert Liu, MD, MPH (Co-Investigator):
Dr. Liu will be responsible for overseeing technology development with our web developer, who will be adapting the MyPrEP website. He will also assist with scientific design of research protocols. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through in-person meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results.

Hyman Scott, MD, MPH (Co-Investigator):
He will provide overall operational oversight of the clinical research team at Bridge HIV. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through in-person meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results.

EXHIBIT B
TO SUBCONTRACT/SUBAWARD AGREEMENT
BUDGET

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 09/07/23	THROUGH 09/06/25	
List PERSONNEL *(Applicant organization only)* Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits								
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Susan Buchbinder	PD/PI	3.60			212,100	63,630	23,543	87,173
Albert Liu	Co-PI	1.20			212,100	21,210	7,848	29,058
Hyman Scott	Co-PI	1.20			212,100	21,210	7,795	29,005
						0	0	0
	SUBTOTALS					106,050	39,186	145,236
CONSULTANT COSTS								
								0
EQUIPMENT *(Itemize)*								
								0
SUPPLIES *(Itemize by category)*								
								0
TRAVEL 0								
								0
INPATIENT CARE COSTS								0
OUTPATIENT CARE COSTS								0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*								
								0
OTHER EXPENSES *(Itemize by category)*								
								0
CONSORTIUM/CONTRACTUAL COSTS								0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*							DIRECT COSTS	**145,236**
CONSORTIUM/CONTRACTUAL COSTS				22.46%			FACILITIES AND ADMINISTRATIVE COSTS	32,623
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								**177,860**

Total budget not to exceed $177,860.

EXHIBIT C
TO SUBCONTRACT/SUBAWARD AGREEMENT

FLOW DOWN PROVISIONS

Refer to the following pages.

Docusign Envelope ID: 878C1F25-FF3E-40DB-90B5-ACC2E062A96E Case 1:25-cv-10814-WGY Document 12-35 Filed 04/04/25 Page 43 of 84

Recipient Information

1. Recipient Name
PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.
13300 CROSSROADS PKWY N
STE 450
CITY OF INDUSTRY, CA 91746

2. Congressional District of Recipient
32

3. Payment System Identifier (ID)
1952557063A1

4. Employer Identification Number (EIN)
952557063

5. Data Universal Numbering System (DUNS)
082199324

6. Recipient's Unique Entity Identifier
L4EEW9SQX2F6

7. Project Director or Principal Investigator
Susan Buchbinder, MD
Director
Susan.Buchbinder@sfdph.org
628-217-7479

8. Authorized Official
Adam Abate
aabate@helunahealth.org
562-222-7804

Federal Agency Information

9. Awarding Agency Contact Information
Julie M. Bergerud
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH
julie.bergerud@nih.gov
301-827-6184

10. Program Official Contact Information
Michael J Stirratt
Chief, Adherence To Treatment & Prevention Program And Hiv Small Business Program (sbir/sttr)
NATIONAL INSTITUTE OF MENTAL HEALTH
stirrattm@mail.nih.gov
240-627-3875

Federal Award Information

11. Award Number
1R34MH132405-01

12. Unique Federal Award Identification Number (FAIN)
R34MH132405

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/07/2023 **– End Date** 09/06/2025	
20. Total Amount of Federal Funds Obligated by this Action	$521,875
20 a. Direct Cost Amount	$482,440
20 b. Indirect Cost Amount	$39,435
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$521,875
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$521,875
26. Project Period Start Date 09/07/2023 **– End Date** 09/06/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$521,875

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Christine Clarkson

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R34MH132405-01

Principal Investigator(s):
Susan Buchbinder, MD

Award e-mailed to: pdale@helunahealth.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $521,875 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PUBLIC HEALTH FOUNDATION ENTERPRISES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R34MH132405. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Christine Clarkson
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
Federal Direct Costs	$482,440
Federal F&A Costs	$39,435
Approved Budget	$521,875
Total Amount of Federal Funds Authorized (Federal Share)	$521,875
TOTAL FEDERAL AWARD AMOUNT	$521,875
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$521,875

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$521,875	$521,875

Fiscal Information:

Payment System Identifier:	1952557063A1
Document Number:	RMH132405A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023
MH	8472592	$521,875

NIH Administrative Data:
PCC: 9A-ASGA / **OC**: 41021 / **Released**: Clarkson, Christine 08/30/2023
Award Processed: 09/07/2023 12:06:30 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34MH132405-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R34MH132405-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

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d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R34MH132405. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated

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funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by

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persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R34MH132405-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION - HUMAN SUBJECTS:

In the absence of certification of IRB approval for Aim 3 for this project, this award is issued with the following restriction: only activities that are clearly severable and independent from Aim 3 activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46, and certification of IRB approval has been submitted to and accepted by the National Institute of Mental Health (NIMH). Failure to comply with this term may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

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Funds included in this award for research involving human subjects in Aim 3 in this project are restricted pending acceptance of certification of IRB approval for Aim 3 by the NIMH. Funds will not be available for carryover under the expanded authorities or Federal Demonstration Partnership without the written prior approval of the NIMH. In addition, no funds may be drawn down from the Payment Management System or expended for any research involving human subjects until the NIMH has accepted the certification of IRB approval.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-20-141 which can be referenced at: PA-20-141: Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (R34 Clinical Trial Optional) (nih.gov)

CHANGE TO A MULTIYEAR FUNDED AWARD:
Although the application was submitted as a 2-year grant request, in order to meet Institute program priorities and objectives within Fiscal Year 2023, this grant has been converted to a multi-year funded award, with all years of funding provided in the current fiscal year. Special monitoring requirements specific to multiyear funded awards, including the progress report due on or before the anniversary of the budget/project period start date of the award, are detailed in Section III in this Notice of Award.

MULTI-YEAR FUNDED REQUIREMENT:
This grant may be deemed materially non-compliant if annual RPPRs are not submitted on September 1st each year. Further enforcement actions may be necessary in accordance with the NIH Grants Policy Statement Section 8.5 (http://grants.nih.gov/grants/policy/nihgps/index.htm).

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **Department of Public Health, City and County of San Francisco (DPH/CCSF).**

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 6/20/23. It is expected that 60 of the 60 total projected participants will be recruited by 8/1/25. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

DATA AND SAFETY MONITORING: Study ID 419992
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events

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as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

Each RPPR submitted is expected to include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and a summary of any safety recommendations from the IRB reviews and any actions taken based on the recommendations.

GCP TRAINING:
NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated 5/4/22 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

HUMAN SUBJECTS RESEARCH:
This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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SPREADSHEET SUMMARY
AWARD NUMBER: 1R34MH132405-01

INSTITUTION: PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 1
Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
TOTAL FEDERAL DC	$482,440
TOTAL FEDERAL F&A	$39,435
TOTAL COST	$521,875

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	11%
F&A Cost Base 1	$148,920
F&A Costs 1	$16,381
F&A Cost Rate 2	13%
F&A Cost Base 2	$147,557
F&A Costs 2	$19,182
F&A Cost Rate 3	13%
F&A Cost Base 3	$29,784
F&A Costs 3	$3,872

EXHIBIT D
TO SUBCONTRACT/SUBAWARD AGREEMENT

FORM OF INVOICE

Please send monthly invoices to Tyler Norgord at TNorgord@helunahealth.org.

The final invoice must be marked FINAL.

The final invoice is due by October 5, 2025.

EXHIBIT E
TO SUBCONTRACT/SUBAWARD AGREEMENT

CERTIFICATE OF INSURANCE

Refer to the following page.

City & County of San Francisco
London N. Breed, Mayor

Office of the City Administrator
Carmen Chu, City Administrator
Matt Hansen, Director, Risk Management

March 20, 2024

Heluna Health
Attn: Adam Abate
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746-3505

RE: MyPrEP Plus: Debelopment and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women
Program/CID # 1067.0101

This letter certifies that the City and County of San Francisco is self-insured and self-funded for the following insurance coverages, which cover clinicians with the Department of Public Health listed on the attached schedule.

General Liability insurance in the amount of $1,000,000 per occurrence and $2,000,000 general aggregate for bodily injury, property damage, and personal injury to third parties for liability arising out of the City's negligence in performance of this agreement.

Automobile Liability insurance with limits not less than $1,000,000 combined single limit per accident for bodily injury and property damage including owned, and non-owned and hired auto coverage as applicable.

Workers' Compensation in statutory amounts with Employer's Liability of $1,000,000 per accident, injury or illness.

Professional Liability including Medical Malpractice and Errors & Omissions with limits not less than $1,000,000 each claim.

The City and County of San Francisco's self-insurance program is not commercial insurance and has no legal capacity to name another entity as additional insured.

Sincerely,

Matt Hansen
Director

cc: Brett Poe, SFDPH

EXHIBIT C



03/20/2025

Peter Dale
PUBLIC HEALTH FOUNDATION ENTERPRISES
pdale@helunahealth.org

Dear Peter Dale:

Effective with the date of this letter, funding for Project Number 5R01MH119956-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 04/26/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 12:02:04 -04'00'

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT D

Docusign Envelope ID: 1CE6E8AE-7F96-43E2-BF70-4FBCA150BB49

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

March 24, 2025

William McFarland, MD
Professor
SHINE Strong: Building the pipeline of HIV behavioral scientists with expertise in trans population health
SFDPH Center for Public Health Research
25 Van Ness Ave Suite 500
San Francisco, CA 94102
Willi_mcfarland@hotmail.com

Subject: Termination Letter: Notification of Termination

Dear William McFarland,

We are writing to formally notify you that Heluna Health received a termination letter from National Institutes of Health on Friday, March 21, 2025 for Contract 5R25MH119858-05 (HH Project # 0761.0105) to cease all activities associated with this project effective March 21, 2025.

Cost resulting from financial obligations incurred after termination of this project are not allowable. To comply with this termination, Heluna Health is initiating the closeout requirements for this project.

To facilitate the closeout process, your client support team will schedule a meeting with you to discuss the steps for closeout, such as staff time allocation; vendor management; final report; expenditures; equipment; etc.

Even though this is one project in your portfolio of projects, we understand the impact this termination can have on the staff and the clients that you have supported, built relationships with as well as, providing services that created health and well-being in our communities throughout California.

We value your contributions, and we look forward to our continued partnership.

Should you have any questions about this letter, please contact Adam Abate at aabate@helunahealth.org and 562-222-7804.

Please acknowledge receipt of this termination letter by signing below and returning a copy to us by March 25,2025.

Thank you for your cooperation and understanding.

Sincerely,

DocuSigned by:
Blayne Cutler
849ACF087DB74D2...
Blayne Cutler, MD
Chief Executive Officer

CC:
Rochelle McLaurin
Johnson Troung

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

Shelia Elahee
Adam Abate

Acknowledgement:

Willi McFarland

Print Name and Title

Willi McFarland 25 March 2025

Signature and Date

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

February 28, 2025

Maria G. Diaz
The Regents of the University of California, Irvine
160 Aldrich Hall
Irvine, CA 92697-7600

Dear Ms. Diaz,

Funding for Project Number 5DP2AI164315-04 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/06/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5DP2AI164315-04 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.

You must submit a request for such review to Dr. Matthew J. Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Matthew J. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Emily B. Linde -S

Digitally signed by Emily B. Linde -S
Date: 2025.02.28 17:35:13 -05'00'

Emily Linde

Director, Grants Management Program
National Institutes of Allergy and Infectious Diseases

[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT F



03/20/2025

PETER DAVID DALE
PUBLIC HEALTH FOUNDATION ENTERPRISES
pdale@helunahealth.org

Dear PETER DAVID DALE:

Effective with the date of this letter, funding for Project Number 5R01MH128049-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/30/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT G



March 18, 2025

Olive T. Giovannetti
The Regents of the University of California, San Francisco
Olive.giovannetti@ucsf.edu

Dear Olive T. Giovannetti:

Effective with the date of this letter, funding for Project Number 1R01 AI181732-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 18, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.19 21:54:59 -04'00'

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT H

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# UM2HD111102
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY
TALLAHASSEE, FL 32306

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

7. Project Director or Principal Investigator
Lisa B Hightow-Weidman, MD (Contact)
Professor
lhightowweidman@fsu.edu
850-644-3296

8. Authorized Official
Stacey Patterson

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
Denise Russo
Program Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
drusso1@mail.nih.gov
301-435-6871

Federal Award Information

11. Award Number
5UM2HD111102-03

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR Part 52

14. Federal Award Project Title
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$11,647,748
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,647,748
26. Project Period Start Date 01/25/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$36,023,354

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Cooperative Agreement
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-03 REVISED

Principal Investigator(s):
Lisa B Hightow-Weidman (contact), MD
Sybil Hosek, PHD

Award e-mailed to: SRA-Pre@fsu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$829,730
Fringe Benefits	$266,026
Personnel Costs (Subtotal)	$1,095,756
Consultant Services	$387,198
Materials & Supplies	$44,168
Travel	$56,400
Other	$2,104,186
Subawards/Consortium/Contractual Costs	$5,908,978
ADP/Computer Services	$30,000
Federal Direct Costs	$9,626,686
Federal F&A Costs	$2,021,062
Approved Budget	$11,647,748
Total Amount of Federal Funds Authorized (Federal Share)	$11,647,748
TOTAL FEDERAL AWARD AMOUNT	$11,647,748
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$11,647,748	$11,647,748

Fiscal Information:

Payment System Identifier:	1596001138A1
Document Number:	UHD111102A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
HD	8014710	$8,647,748
MH	8472592	$1,000,000
DA	8472628	$2,000,000

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41029 / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:22:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM2HD111102-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5UM2HD111102-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) UM2HD111102. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines. This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to

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Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) National Institute On Drug Abuse (NIDA) National Institute Of Mental Health (NIMH)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently

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the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-03 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.

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- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

RESTRICTION: This award is being made without a currently valid certification of Institutional Review Board (IRB) approval and is issued with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval. No funds may be drawn down from the Payment Management System and no obligations may be made against Federal funds for any research involving human subjects prior to issuance of a revised Notice of Award rescinding this restriction.

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2022 and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

SUBPROJECT: Subproject funding information is available via the NIH RePORTER System.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 “NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research”. All NICHD applications which include Clinical Trials must include a Data Safety

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Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

DISSEMINATION: The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the application dated 11/05/2022 and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of their knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

RISK ASSESSMENT:

Clinical Trial Study/Studies:

416802

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416804

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416806

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual

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RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416813

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **HIGH** risk requiring increased oversight by NICHD. A **quarterly update** on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones are due **three times a year** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416814

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **MEDIUM** risk requiring increased oversight by NICHD. An update on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones will be due **once a year (generally halfway through the budget period)** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416815

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

SPREADSHEET SUMMARY
AWARD NUMBER: 5UM2HD111102-03 REVISED

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 3
Salaries and Wages	$829,730
Fringe Benefits	$266,026
Personnel Costs (Subtotal)	$1,095,756
Consultant Services	$387,198
Materials & Supplies	$44,168
Travel	$56,400
Other	$2,104,186
Subawards/Consortium/Contractual Costs	$5,908,978
ADP/Computer Services	$30,000
TOTAL FEDERAL DC	$9,626,686
TOTAL FEDERAL F&A	$2,021,062

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TOTAL COST	$11,647,748

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	54%
F&A Cost Base 1	$3,742,708
F&A Costs 1	$2,021,062

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EXHIBIT I

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:31 AM
To: Sit, Jimmy <Bao.Sit@ucsf.edu>
Subject: Grant Termination Notification

This Message Is From an External Sender

This message came from outside your organization.



3/21/2025

Bao Sit
University Of California, San Francisco
bao.sit@ucsf.edu

Dear Bao Sit:

Effective with the date of this letter, funding for Project Number 5R25MH129290-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 36

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF THERESA A. MALDONADO

I, Theresa A. Maldonado, declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the system-wide Vice President for Research & Innovation at the University of California (UC), Office of the President. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UC staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I have served as the Vice President for Research & Innovation at UC since 2020. In addition to my current role, I have a Ph.D. in electrical engineering and over 30 years' academic experience. As Vice President for Research & Innovation, I lead UC researchers and administrators in research policy, funding for systemwide programs, and the innovation and entrepreneurship ecosystem. We work to build UC-wide partnerships, help shape effective

policies and provide a strong voice nationally for research and innovation on behalf of UC. As the systemwide leader for research and innovation, I work very closely with the Vice Chancellors for Research from each UC campus, and I am in regular contact with them to identify any issues impacting UC systemwide research, including concerns related to research funding.

UC and Its Research Mission.

4. The University of California ("UC") has 10 research-intensive campuses, 21 health professional sciences schools, five NCI-designated cancer centers, and six academic medical centers are widely recognized as among the best in the nation. They are international leaders in the education of health professionals, in research that develops new cures and treatments, and in public service that provides healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more.

5. Every year, UC and its researchers submit thousands of grant applications for review, approval, and funding by the NIH. As world leading researchers, more than 1,000 UC faculty members serve annually on numerous NIH study sections and advisory councils to assess grant applications for scientific and technical merit. NIH contract and grant funding support many of the clinical trial studies at UC's six medical centers.

6. The research mission at UC includes, but is not limited to, allocated funding for staffing, clinical trials, dissemination of results, public outreach, teaching and training students

and others, equipment, and numerous other activities to fulfill the research mission and serve the people of California and the United States.

Reliance on NIH Funding

7. In fiscal year 2024, UC was awarded over $2 billion through the National Institutes of Health ("NIH") to support more than 5000 research projects.

8. The work done by UC's research-intensive campuses, academic medical centers, and health professional sciences schools on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs.

9. UC's campuses, academic medical centers, health professional schools, cancer centers and the laboratories it manages and operates provide considerable employment benefits in the Science, Technology, Engineering, Mathematics, and Medicine ("STEMM") workforce to the California economy. UC estimates that NIH funding supports thousands of employees at its medical centers and campuses, including clinical and professional staff, post-doctoral and graduate student researchers, laboratory technicians, and engineers.

Typical Process for NIH Grant Awards

10. The Sponsored Projects Office at each UC location works with researchers to submit grant applications and tracks grant applications and awards. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is

then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

11. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether to recommend a grant for funding is made. After the advisory council meets, the relevant institute's Director typically approves the recommended grants, and a Notice of Award is promptly issued confirming the grant will be funded.

12. The budget process at UC research institutions relies, in part, upon the NIH grant application, review, and approval cycle.

Delays and Irregularities in the Processing of NIH Grant Applications

13. Since late January 2025, UC has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or not scheduled, and grant application scoring has been significantly delayed.

14. The estimated value of just the NIH grant proposals that have been submitted for review by the five UC Health Centers as of December 31, 2024, and that have not yet been acted upon is approximately $563 million. Grant applications awaiting study sections before July 1, 2025, had an annual value of approximately $312 million, while grant applications awaiting NIH advisory councils and Notices of Awards amounted to approximately $251 million in annualized value.

15. UC has not received formal notices of awards for many of these grant proposals. For others, UC has only received a notification that proposals are "paused" or "under review."

Terminations of NIH Grants.

16. Since February 20, 2025, UC's research institutions have had at least thirty-one NIH grants terminated, amounting to over $37 million. Among these was a grant for over $50 million in funding for a UC Davis research project investigating the biological risk factors for dementia among target populations with early signs of cognitive dysfunction, including white, Hispanic, and black participants that had already enrolled over 1,700 participants, and a grant to UCSF for a project studying the effectiveness and adverse consequences of a vaccine for shingles, a disease that one in three Americans are likely to develop in their lifetimes.

17. The termination notices for these grants typically state that the "award no longer effectuates agency priorities." In my time at UC, to the best of my knowledge, NIH grants have not generally been terminated on this basis.

18. Many of the termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, most UC Principal Investigators were not given notice of any opportunity to submit "corrected" grant materials to align with agency priorities.

Impacts of Funding Delays and Grant Terminations.

19. The delays in funding decisions and evaluation of grant applications as well as the grant terminations have already caused numerous and critical harms to UC.

20. The delays and terminations have disrupted ongoing research, as well as setting back significant UC research projects. Funding gaps have forced researchers to abandon important research studies and terminate key personnel. Some of these studies involve clinical trials of medications or procedures, and terminations will delay UC's ability to identify and

deliver life-changing care for patients suffering from diseases such as Alzheimer's disease, Type 2 Diabetes, and HIV.

21. Once canceled, much research cannot immediately resume. Many of these projects entail longitudinal studies. When scientific studies stop in full swing, their partial results often lose validity. Without funding, labs languish, and specimens spoil. And once laid off, people with project-specific knowledge and experience may not return.

22. The UC system has instituted a system-wide hiring freeze on new faculty and staff. Top-ranked departments across UC campuses in chemistry, biology, public health, and more have reduced their graduate student classes. UC departments have had to consider rescinding offers of funding to some students admitted to doctoral programs. To the extent possible, UC has arranged for emergency funding to cushion the impact of interrupted federal funding and maintain salary support for affected graduate students and trainees. This relief is aimed at bridging those personnel to give them time to complete their graduate programs or to secure other funding or employment.

23. These funds are being diverted from other important needs, such as deferred maintenance and strategic investments. Without expected grant funds, UC will be challenged in meeting the expenses associated with overseeing research facilities which make these significant research projects possible and economically viable.

24. The delays in funding and terminations also have harmed the UC's educational and research mission. Doctoral students, postdoctoral researchers, faculty, and staff from around the world collaborate with or come to California to join the UC research enterprise. Future recruitment of these young scientists and researchers will be negatively impacted by diminished funding and arbitrary terminations aimed at international collaboration and research projects.

Further, terminations have specifically impacted the communities that come to UC for clinical trials and other community health interventions. Midstream terminations of long-term projects meant to reduce health disparities in projects like maternal mortality, the spread of HIV/AIDS, and services to other underserved communities directly undermines the trust necessary to convince individuals to participate in UC research projects.

April 3, 2025

DocuSigned by:
Theresa A Maldonado
537FE71B2CD94F8...

THERESA A. MALDONADO

EXHIBIT 37

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

Background

1. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I served as director of NIGMS from 2003 to 2011. The purpose of NIGMS is to support research and training of scientists across a wide range of areas, including biochemistry, cell biology, genetics, computational biology, bioinformatics, anesthesiology, wound healing, and burn and trauma research. The United States' ability to effectively treat, diagnose, manage, and ultimately cure diseases requires an understanding of their underlying mechanisms and biology. NIGMS' investments in fundamental basic research have supported 90 Nobel prizes and improvements in treatments for diseases including heart disease, cancer, neurological diseases associated with aging, sepsis, and many others.

2. Throughout my career, I have also helped guide scientists at the beginning of their independent careers as they sought to compete for NIH funding. Prior to coming to NIH, I was Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins

University School of Medicine. In this role, I conducted research in partnerships with graduate students including combined MD/PhD students, and postdoctoral fellows with much of this work supported by NIGMS and other NIH institutes.

3. In 2011, I left NIH in 2011 to come to the University of Pittsburgh with my wife, a leading breast cancer screening expert who was recruited to this institution. Here, I have continued to conduct some NIH-funded research in the area of computational biology and also have helped to manage a range of programs that receive NIH funding.

4. Since January 20, 2025, delays and terminations in NIH funding have dramatically disrupted the work of advancing biomedical research and training the next generation of scientists. Steps that have contributed to these disruptions have included the "pausing" of grant-making processes at NIH, the extremely slow release of continuing awards for multi-year grants, the disruption of the regularly scheduled national Advisory Committee meetings required to approve grant applications prior to funding, the disruption of the peer review "study section" meetings required for grant application evaluation and prioritization, and other steps. More recently, these have included direct terminations of specific grants based not on lack of performance or any other irregularities, but claims that the aims of these grants no longer aligned with NIH's priorities.

5. Based on my personal analysis of publicly available data (through the NIH Reporter website), over $3.3 billion of NIH funding that would typically have been disbursed through NIH's grant making and grants management process by this point in the year has not been. Through March 1st, more than $1.8 billion of the funding is missing from the normal funding of continuation awards for multi-year grants. Similarly, more than a billion of the

funding is missing in new grant funding from grant applications that undergo the highly competitive scientific peer review described below.

6. Similarly, scientific colleagues have received grant terminations that have completely upended the work of their research labs, staff, and students. For example, all the awards for the Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Potential have apparently been terminated. This program is intended to do preparatory work for viruses and other pathogens that might cause pandemics in the future; and again went through a competitive award process. These awards were terminated on the grounds that the COVID pandemic is over and, therefore, this research is no longer needed. It is hard for me to understand the logic of the termination of these forward-looking looking grants when the risk of a pandemic from COVID and other viruses persist.

7. As further described below, these disruptions and terminations are completely contrary to my previous experience both at and with the National Institutes of Health.

Role of NIH in Biomedical Research at Universities

8. Since the 1930s, the NIH and its predecessor agencies have supported the advancement of the United States' understanding of human disease and disability by funding training and research. In 1944, Congress formally created the NIH as part of the Public Health Service in order to encourage scientific institutions, other public institutions, and scientists in the conduct of research and demonstrations related to the causes, diagnosis, treatment, control, and prevention of physical and mental illnesses and disability. Congress specifically authorized support of research through grants to universities, hospitals, laboratories, and other public or private institutions for research projects after review by the NIH institutes' national advisory

councils. Similarly, Congressional funding for training and fellowships dates back more than 50 years.

9. Since the 1930s, Congress has also added new institutes and centers focusing on different diseases, organ systems, life stages, or other aspects of biomedical research. For example, Congress specifically created NIGMS in 1962 to cover biomedical research of interest to two or more existing institutes or that are not covered by other institutes. Today, there are 27 institutes and centers as well as the Office of the Director within NIH. With the exceptions of the Center(s) for Scientific Review, the Center for Information Technology, and the NIH Clinical Center, the individual institutions, centers and the Director have the authority to issue grants to researchers through their organizations.

10. Today, Congress appropriates more than $47 billion to the NIH's institutes and centers to advance biomedical research, including through grants to extramural researchers and institutions. Over 85 percent of NIH's annual funding to advance biomedical research powers the more than 38,000 principal researchers, research projects, and trainees in external organizations across the United States.

11. NIH grants are typically awarded for an average of four years because the advancement of biomedical research benefits significantly from stable funding across a number of years. Very few research projects of any scientific significance can be completed in less than two years. Generally, grants are not fully funded all at once. An initial award in one fiscal year is followed by continuation (or non-competitive renewal) awards in subsequent years pending submission of an acceptable scientific and financial progress report. Thus, at any given point in time, about 80 percent of NIH's external funding is committed to existing research, support for the NIH intramural research program, or other costs such as NIH operations. The remaining 15

percent is available for new grant applications and the competitive renewal of long-term research projects. Stability is important to scientific investigation, particularly to encourage researchers to pursue innovation and risk in biomedical research. NIGMS has developed a variety of methods to provide stable funding for researchers so that productive or promising projects are not interrupted.

12. The stability of these grants also furthers the building of research capacity and the training of both graduate students and early-career scientists. A large proportion of pre- and postdoctoral scientists are supported during some or all of their training periods via research project grants rather than training awards. This situation exists because many members of research teams funded by NIH research project grants include graduate students and postdoctoral researchers who engage in research as a key component of their training activities.

13. Through the Ruth L. Kirschstein National Research Service Awards and other programs, Congress has historically directed funding to public and private institutions specifically for the pre-doctoral and post-doctoral training of individuals to undertake biomedical research. Since 1972, such funding has included explicit provisions directed toward increasing the percentage of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) into fields of biomedical research. This is particularly important since project selection and other aspects of research related to health can depend on the life experiences of those engaging in research.

14. At the direction of Congress, NIH and institutes like NIGMS have also increased their funding in specific research areas. For example, this is true for research related to HIV/AIDS which has been coordinated through the NIH Office of AIDS Research. When I was a department chair at Johns Hopkins School of Medicine in the 1990s, there were serious

discussions about where non-AIDS patients were going to be treated as beds at Johns Hopkins Hospital filled with AIDS patients. But with the support of NIH, the United States developed an understanding of basic biochemistry and virology of the HIVvirus, identified a variety of drug targets and, subsequently, developed drugs that have turned HIV infection from a death sentence into a treatable chronic condition. For some patients, the newest research has achieved a true cures to their HIV infection. Considering continued outbreaks and deaths from HIV/AIDS, the potential to reduce this public health risk in vulnerable communities and internationally is profoundly important.

NIH Funding Priorities Based on Congressional Direction & Scientific Assessment

15. In addition to Congressionally directed funding, the Director of the NIH and each institute and center engages with its advisory council, policy makers, scientific and professional societies, and other public stakeholders to identify agency funding priorities. Congress has directed the NIH to assemble accurate data to assess research priorities including information to evaluate scientific opportunities and public health disease burdens, including progress in reducing health disparities. NIH publicizes the data on the study populations of clinical research funding by its institutes and centers on its website. NIH also considers disease burden in the United States and the potential for return on investment to the United States; rare diseases and conditions; and the biological, social, and other determinants of health contribution to health disparities in identifying research priorities. These priorities are reported to Congress and publicized on its website via the NIH strategic plan.

16. At NIGMS, the institute specifically engaged in scientifically based strategic planning on a five-year basis. While I was NIGMS director, we developed the first formal

NIGMS strategic plan, NIGMS Strategic Plan 2008-2012: Investing in the Future.[1] This plan was developed through extensive interactions with stakeholders from different communities around the country and staff across NIGMS and NIH.

17. Once agency priorities have been identified, each institute and center issues notices of funding opportunities (NOFOs) for specific grant mechanisms, some of which are targeted to specific areas and some are open-ended invitations to investigators to propose problems of interest and specific approaches that fall within the given NIH institute or center's mission.

18. As further described below, when reviewing applications for NIH funding, both the institute and its advisory council explicitly consider whether an application is consistent with its mission and scientific priorities identified in its strategic plan.

Review of External Funding at NIH Based on Scientific Merit and Strategic Plan

19. The NIH receives approximately 50,000 grant applications per year. NIGMS alone awards and manages more than 4,500 grants on average and reviews nearly 1,000 grant applications (in addition to those reviewed by study sections at the NIH's Center for Scientific Review) received in response to NOFOs. As part of the NIH mission to advance biomedical research, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

20. Notices of funding opportunities explicitly incorporate the criteria used to assess scientific and technical merit of each grant application. Criteria can include the scientific significance of the proposed project, including the strength of the scientific premises of the grant;

[1] NAT'L INST. GEN. MEDICAL SCIENCES, INVESTING IN DISCOVERY (2007), https://www.nigms.nih.gov/sites/nigms/files/migrated/NIGMS-strategic-plan-2008-2012.pdf

the investigators' expertise and resources; the potential innovative impact of the proposed research; and whether there is a rigorous and feasible approach to address the aims of the project. Other criteria include justification of the proposed budget and duration in relation to the proposed research. For clinical research, patients need to be protected from research risks including the risk of needing to stop the research and the application also needs to address the appropriateness of the proposed study population.

21. When a scientist submits a grant application through their organization, the NIH assigns the application to a study section at the Center for Scientific Review for peer review or to study sections at a specific NIH institute or center for more scientifically specialized topics. Study sections are composed of 20-30 independent researchers from the scientific community who have the expertise to assess topics such as Basic Mechanisms of Diabetes and Metabolism or Chemical Biology and Probes. There are approximately 250 standing study sections that meet at least three times a year on specified topics. Special emphasis panels or study sections also meet to review applications for more specialized programs or for projects that fall outside an existing study section.

22. The study section meets, reviews, and scores an application for scientific and technical merit. The review is time intensive and done on a mostly voluntary basis. Each reviewer on a study section is assigned between 4-10 applications. Each application has two primary reviewers and an additional reader who present the application for discussion at one-to-two-day meetings. Scores can significantly shift as key features or flaws are noted. Scores from different study sections are normalized so that scores from different study sections can be compared. Fewer than half of applications make it through this part of the process with a significant chance of being selected for funding.

23. Advisory councils from each institute or center then meet and review the grant critiques (called summary statements) with NIH staff to ensure that the first level of peer review appears to have proceeded appropriately and to assess alignment of the application with the institutes' funding priorities. Advisory councils are committees of 10-12 academic scientists and other experts (e.g., patient advocates, economists) who typically serve four-year terms and are appointed by the Secretary of Health and Human Services. Advisory councils provide oversight of the first stage of peer review and make recommendations about applications that should be given higher or lower priority given the state of science in a given institute or center's field, and the mission and extant portfolio of said institute. Advisory councils typically meet three times a year with meetings scheduled years in advance. These meetings align with the normal funding cycles for grant review process.

24. Finally, each institute and center's director make funding decisions with the advice of program officers and senior leaders in the institute or center. Funding decisions are largely based on peer review scores, but also with consideration regarding the existing grant portfolio, a center's publicized priorities, or recommendations of staff. Budgets are adjusted based on peer review, staff recommendations, and the availability of Congressionally appropriated funds. Grants are then awarded to each researcher's institution.

25. Before this year, I have never observed nearly all study sections and advisory councils canceled for a funding cycle. On January 21, the Acting Secretary of Health and Human Services informed NIH that all notices in the Federal Register would need to be approved by a Presidential appointee. This is important because study sections and advisory councils are committees subject to the Federal Advisory Committee Act (FACA), a transparency statute enacted in 1972. My understanding is that this law was intended to prevent the federal

government from receiving advice in secret. Here, it was being used to block normal grant-making processes. Approval of grant applications and peer review is required in order for an application to be eligible for funding.

Continued Funding at NIH Based on Scientific Merit & Performance

26. NIH staff, such as grant management officers and scientific review officers, are also assigned to manage the more than 59,000 grants that NIH manages in a year. In 2023, these grants supported 38,000 principal investigators and more than 300,000 researchers at more than 2,500 institutions across the country.

27. Due to the nature of funding scientifically significant but innovative and sometimes risky nature of biomedical research, investigators have the flexibility to adjust their research efforts depending on ongoing discoveries or other developments in the scientific field. But the NIH's staff still review annual progress reports to assess whether or not the researcher has continued to make progress on the project appropriate for what was in their grant application.

28. NIH program officers and grants management specialists must review these reports and approve a new year of funding through an administrative review without the involvement of study sections and advisory councils. As mentioned above, due to the importance of funding stability in advancing scientific investigation—absent scientific misconduct or other significant events—these funding streams are almost always approved in a timely manner as grants come up for review based on their start date.

Rarity of Grant Terminations

29. The NIH rarely terminates grants. I do not recall any instances of such terminations by NIGMS during my nearly eight years as director. Prior to 2025, I am only aware of two such terminations in subsequent years. One involved an aging investigator who was not

longer able to conduct the research (and who died shortly thereafter) and another involved an investigator fired from his university of sexual harassment involving younger scientists.[2]

30. Otherwise, in instance of concerns about performance of the grant, rather than terminating a grant, the NIH has generally discussed with the grantee or with others at the grantee organization to pursue corrective action prior to making any additional awards.

31. Finally, in instances of scientific misconduct, the NIH still seeks to preserve the results of the research if possible. Scientific misconduct includes, but is not limited to, fabrication of the data and results from a scientific study or plagiarism of another person's processes and results without giving appropriate credit.[3] Under many circumstances, misconduct investigations, conducted by the grantee organization or their designee, identify problematic scientific publications and push for correction or retractions for impacted publications. But in other instances, publications are cleared by the investigation with no evidence of influence on the publication due to the inappropriate behavior.

Funding Disruptions Devastating, Without Alternatives

32. In the long term, if these disruptions in Congressionally directed funding continue, the biomedical enterprise both in public and private institutions is in danger. As an example of how basic research helps to fuel rapid progress in developing new and safer treatments and prevention strategies, the U.S. Food & Drug Administration recently approved a

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[2] *See* Amy Harmon, *Chicago Professor Resigns Amid Sexual Misconduct Investigation*, N.Y.TIMES (Feb. 2, 2016), https://www.nytimes.com/2016/02/03/us/chicago-professor-resigns-amid-sexual-misconduct-investigation.html

[3] Office Res. Integrity, *Definition of Research Misconduct*, DEP'T HEALTH & HUMAN SERVS., https://ori.hhs.gov/definition-research-misconduct (last visited on Apr. 2, 2025).

first-in-class non-opioid medicine for mild to moderate pain (suzetrigine, brandname Journavx).[4] This was based on decades of basic and more applied research in NIH-funded academic and private-sector laboratories. The loss of any of the large amount of information or techniques generated from this research would have made approval of this pain medication impossible. Move over, many of the scientists involved— including those in industry—were trained at the NIH or in academic laboratories supported by the NIH. In the long run, these advancements have the potential both to provide a new alternative to treat post-surgical pain, but also to address the demand side of the opioid public health crisis.

33. There are not alternative sources to replace the NIH's more than $40 billion in biomedical research funding. In 2022, the NIH invested more than 25 more times on grants than the next largest funder, the Wellcome Trust based in the United Kingdom.[5] Combining then the next 25 largest funders of biomedical research would not replace the NIH's annual funding of biomedical research. Moreover, as private or non-US based funders, those funders are unlikely to have the same priorities identified by Congress and by US-based researchers and stakeholders.

Conclusion

34. As an undergraduate, graduate student, and postdoctoral fellow, my training and research were supported through research grants to my research mentors. When I started my independent career, my research projects were funded through a then-new program directed to beginning faculty members. The continuity of Congress and the American people's investment in biomedical research via the NIH has been vital to my career path. The United States has

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[4] Press Release, FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain (Jan. 30, 2025), https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain

[5] Nisha Gaind, *How the NIH Dominates the World's Health Research*, 639 NATURE 554 (2025), doi: https://doi.org/10.1038/d41586-025-00754-4

similarly invested in the training and research of numerous students, early career scientists, and faculty in every state and territory. It is a shame that these interruptions in NIH funding now endanger the advancements and institutions powered by those individual researchers.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 2nd day of April 2025, in Gibsonia, PA.

Jeremy M. Berg, Ph.D.
Former Director (2003-2011)
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 38

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

DECLARATION OF RAFAEL JAIME

I, Rafael Jaime, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the President of UAW Local 4811, the labor union representing over 48,000 academic workers across the University of California system. I have personal knowledge of the facts stated below or have obtained them through consultation with our members, stewards, and staff, as well as from institutional correspondence and grievances. If called as a witness, I could and would competently testify to the facts stated here.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Background

3. UAW Local 4811 represents academic workers across the ten campuses and medical centers of the University of California, as well as Lawrence Berkeley National Laboratory. Our members include postdoctoral scholars, graduate student researchers, academic student employees (such as teaching assistants), and other academic researchers. Together, these

workers form the backbone of publicly funded academic research at UC, including research funded by the National Institutes of Health ("NIH").

4. For nearly three decades, UAW 4811 has fought to make UC a better place to work, teach, and conduct research. We bargain for contracts, enforce our members' rights, and organize for dignity in research work and public education.

Reliance on NIH Funding and Harm to Our Members

5. Since late January 2025, we have witnessed mounting disruptions in NIH-funded research across the campuses where our members work. Our members rely heavily on NIH funding streams—either directly, via individual fellowships and training grants (e.g., F31, F32, K99, T32), or indirectly through lab employment supported by faculty-held NIH grants.

6. Delays in funding NIH grants and terminations of grants have had, and continue to have, the following impacts on our membership:

a. *Job Insecurity and Interrupted Appointments*: We have received widespread reports that members' appointments have been shortened, renewal decisions delayed, or start dates rescinded because of uncertainty surrounding NIH funding. Postdocs, academic researchers and graduate student researchers in particular have been told by principal investigators (PIs) that they cannot be reappointed unless or until NIH makes funding determinations that are months overdue. Since March 5 of this year, we have received 17 layoff notices, 2 reductions-in-time, and 6 non-renewals of contracts due to NIH funding cuts and delays. These numbers are sure to increase as the number of cancelled grants increases and awards are further delayed.

b. *Disruption of Research and Academic Progress*: Many of our members report being unable to complete their experiments or thesis research. Some have had to abandon critical data collection due to the unavailability of lab resources. NIH grant uncertainty has caused members to pause ongoing projects, re-scope dissertation topics, and in some cases, consider leaving their programs entirely. At UCSF, a grant to study infectious diseases was suddenly cancelled leaving hundreds of researchers without funding to complete a multi-year study.

c. *Visa and Immigration Risk*: Close to 50% of our postdoctoral and academic researcher, and graduate student membership holds F-1, J-1 or H-1B visas, which require ongoing employment and sponsorship. Multiple members have contacted our union in distress over the prospect of losing visa status due to lapses in funding or expiring contracts. In some cases, union members have sought, with assistance from their union, bridge funding or alternate sponsors to keep from having to leave the country or being deported.

d. *Missed Career Milestones*: Several members planned to apply for K99 or other independent NIH awards this spring but were advised by faculty to delay applications until NIH resumes normal operations. Others missed application windows altogether due to the lack of institutional support for reference letters and compliance review during the funding freeze. We are aware of members who have withdrawn from job searches, declined postdoctoral offers, or may need to delay graduation due to NIH-related instability. In addition, we are aware of members who are seriously exploring opportunities outside the United States as a result.

7. Across the University of California, we are seeing systemic impacts:

   a. Principal Investigators and departments have frozen hiring for NIH-funded postdoc, academic researcher and graduate student positions, or have stated they will imminently need to do this;

   b. NIH-funded labs have been forced to halt experiments and conserve discretionary funds in anticipation of grant denials or terminations, or have stated they will imminently need to do this;

   c. Postdocs, academic researchers and graduate students working on NIH training grants have been left in limbo due to non-renewals;

   d. Our union has fielded an increasing volume of inquiries and grievances regarding shortened appointments, lack of notice, and abrupt changes to work assignments and funding.

8. For example, one of our members, a postdoctoral researcher in infectious diseases, was told by their PI that their appointment could not be renewed after July 7th because the R01 they were funded under was suddenly cancelled. The member is on a J-1 visa and is now at risk of deportation.

9. The member in the above example is just one of over 200 researchers who are being impacted by the cancellation of a single grant at one UC campus.

10. Our members are at the front lines of American biomedical research—developing therapies, conducting basic science, and contributing to public health advancement. Yet their careers are being destabilized by bureaucratic inaction and unexplained political interference.

Irreparable Harm

11. The loss of stability, research continuity, and training momentum is already having lasting effects. Even if NIH resumes normal grant processing and ceases terminating grants tomorrow, the damage done to our members' careers, experiments, immigration status, and trust in the research enterprise is irreversible.

12. Our members represent the future of publicly funded science. The delays are already chilling career interest in postdoctoral research and graduate education, which threatens to create downstream shortages of qualified biomedical researchers and faculty.

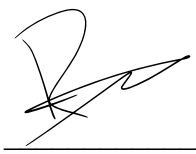
13. Many of the affected members are first-generation scholars or from historically marginalized groups, including those working on NIH-funded disparities research. The disruption has a disproportionate effect on efforts to diversify the biomedical research workforce.

14. The harms fall disproportionately on international scholars, first-generation college graduates, and members of underrepresented communities who cannot weather prolonged uncertainty or self-fund their research careers.

Conclusion

15. The NIH's failure to timely review, approve, or renew grants has caused serious and compounding harm to our members—jeopardizing their work, their livelihoods, and in some cases, their ability to remain in the country. It is undermining the very infrastructure of American biomedical research.

Executed this 2nd day of April 2025 in Los Angeles, CA.



Rafael Jaime
President
UAW Local 4811