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-10814-BEM

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. Exhibits 1-38 are identical to the exhibits previously filed as attachments to the Declaration of Chris Pappavaselio, Doc. No. 12, with four exceptions—Exhibit 10 has been corrected to include omitted appendices; Exhibit 11 has been edited to include additional excerpted pages; and Exhibits 17 and 19 have been updated to reflect

subsequent factual developments observed by the declarants. Exhibits 39-65 have not been previously filed. The exhibits are described 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." This document has been corrected from the version filed as Exhibit 10 of the Declaration of Chris Pappavaselio, so as to include omitted appendices. Doc. No. 12.

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. This document has been edited from the version filed as Exhibit 11 of the Declaration of Chris Pappavaselio, so as to include additional excerpts. Doc. No. 12.

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. This declaration, dated April 13, 2025, replaces the March 31, 2025, version which had been filed as Exhibit 17 to the Declaration of Chris Pappavaselio. Doc. No. 12.

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. This declaration, dated April 13, 2025, replaces the April 2, 2025, version which had been filed as Exhibit 19 to the Declaration of Chris Pappavaselio. Doc. No. 12.

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.

43. Attached hereto as Exhibit 39 is a true and correct copy of a January 21, 2025, document authored by Dorothy A. Fink, then-Acting Secretary of Health and Human Services, with the subject: "Immediate Pause on Issuing Documents and Public Communications – ACTION."

44. Attached hereto as Exhibit 40 is the declaration of Ryan Hutchings, Ph.D.

45. Attached hereto as Exhibit 41 is a true and correct copy of the transcript of the April 3, 2025, deposition of Michelle Bulls taken in the matter of *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025).

46. Attached hereto as Exhibit 42 is a true and correct copy of: Katherine J. Wu, Inside the Collapse at the NIH, The Atlantic (Feb. 27, 2025), https://www.theatlantic.com/health/archive/2025/02/nih-grant-freeze-biomedical-research/681853/.

47. Attached hereto as Exhibit 43 is a true and correct copy of three screencaptures from NIH institute websites (National Institute on Deafness and Other Communication Disorders, National Institute of Allergy and Infectious Diseases, and National Institute on Minority Health and Health Disparities), captured between April 12, 2025, and April 14, 2025, each indicating that "all Federal advisory committee meetings have been canceled until further notice."

48. Attached hereto as Exhibit 44 is a true and correct copy of: NIH Grant Review Meetings Cancelled, American Association for Cancer Research (Jan. 23, 2025), https://aacrjournals.org/cdnews/news/2062/NIH-Grant-Review-Meetings-Cancelled.

49. Attached hereto as Exhibit 45 is the supplemental declaration of Denise Barton.

50. Attached hereto as Exhibit 46 is the declaration of Sally Morton.

51. Attached hereto as Exhibit 47 is the supplemental declaration of Jason A. Wilder.

52. Attached hereto as Exhibit 48 is the declaration of Marcus Crawford, Ph.D.

53. Attached hereto as Exhibit 49 is the declaration of Jeni Kitchell.

54. Attached hereto as Exhibit 50 is the declaration of John E. Pool.

55. Attached hereto as Exhibit 51 is the declaration of Susannah Porterfield, Ed.D. and accompanying exhibits.

56. Attached hereto as Exhibit 52 is the declaration of John A. Pelesko, Ph.D. and accompanying exhibits.

57. Attached hereto as Exhibit 53 is the supplemental declaration of John J. Farmer, Jr., and accompanying exhibits.

58. Attached hereto as Exhibit 54 is the declaration of Lakshmi Reddi.

59. Attached hereto as Exhibit 55 is the declaration of Shelley L. Lusetti, Ph.D.

60. Attached hereto as Exhibit 56 is the declaration of Michael E. Richards, M.D., MPA, and accompanying exhibits.

61. Attached hereto as Exhibit 57 is the declaration of Lauren Forrest, Ph.D.

62. Attached hereto as Exhibit 58 is the declaration of Richard Tankersly and accompanying exhibits.

63. Attached hereto as Exhibit 59 is the declaration of Anshuman Razdan, Ph.D.

64. Attached hereto as Exhibit 60 is the supplemental declaration of Bethany D. Jenkins.

65. Attached hereto as Exhibit 61 is the supplemental declaration of Jeremy M. Berg, Ph.D.

66. Attached hereto as Exhibit 62 is the supplemental declaration of Ganesh Raman, Ph.D.

67. Attached hereto as Exhibit 63 is the supplemental declaration of Blake Riggs, Ph.D.

68. Attached hereto as Exhibit 64 is the declaration of Shashank Priya and accompanying exhibit.

69. Attached hereto as Exhibit 65 is the declaration of Harold Collard.

Dated: April 14, 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 counsel for or on behalf of plaintiffs have submitted the foregoing document with the clerk of court for the District of Massachusetts, using the electronic case filing system of the Court. Counsel for Plaintiffs hereby certify that they have served all parties electronically or by another manner authorized by Fed. R. Civ. P. 5(b)(2).

/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.

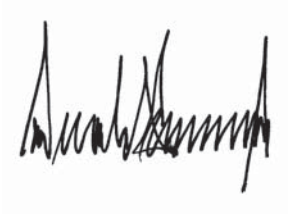
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(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:

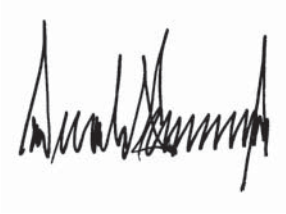
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(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.

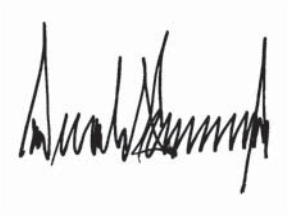
Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(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

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

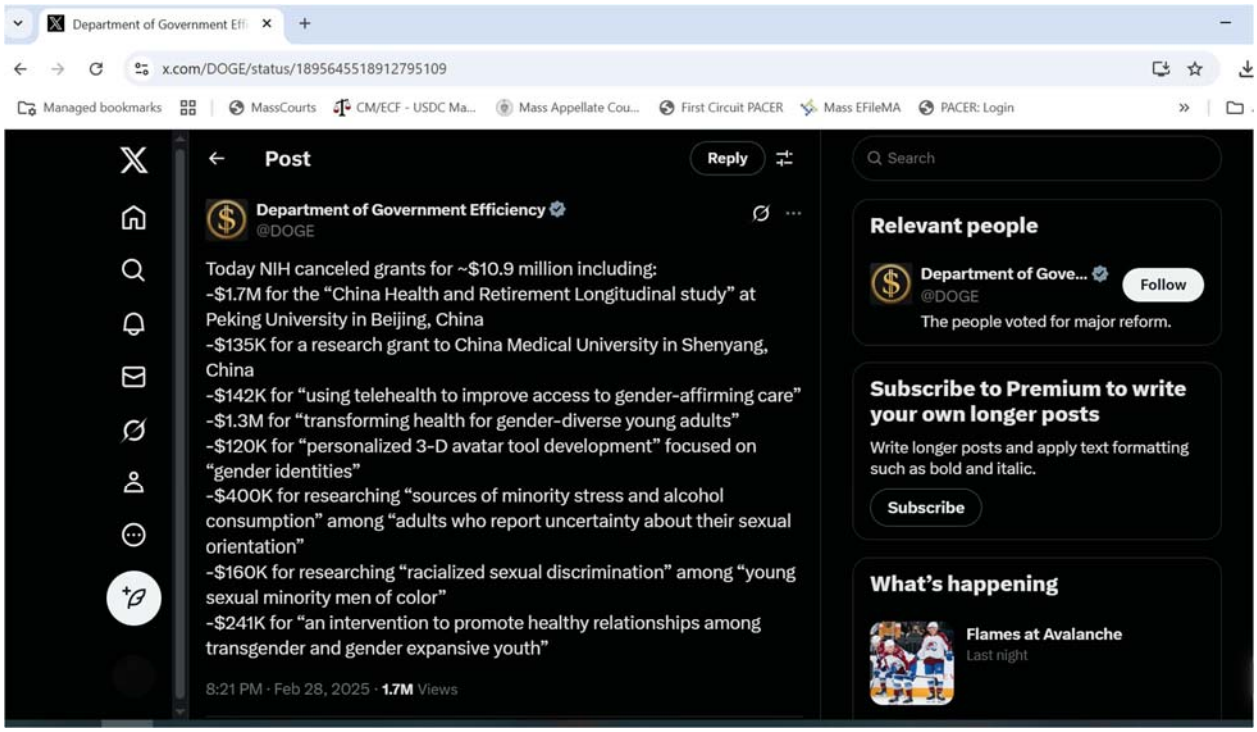

Department of Government Eff
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@DOGE
Today NIH canceled grants for ~$10.9 million including:
-$1.7M for the "China Health and Retirement Longitudinal study" at Peking University in Beijing, China
-$135K for a research grant to China Medical University 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

CONFIDENTIAL

concern, e.g., South Africa, etc.) 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.

- **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

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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

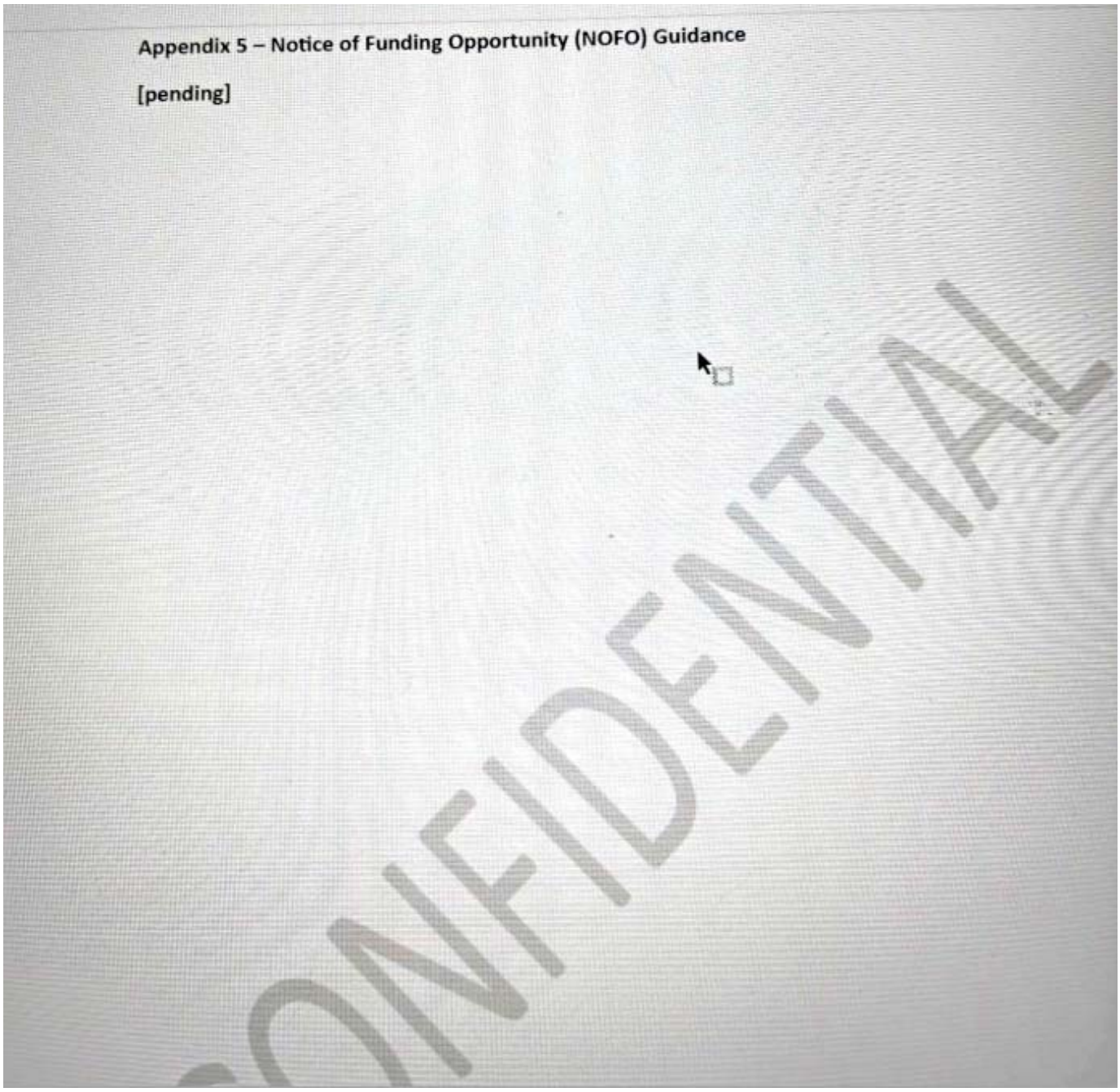
Appendix 2 – Guidance for staff to use on specific programs, awards, supplements.

- **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.
- **Linked (or equivalent) Awards**: If one linked award is terminated, the IC is only required to terminate the specific award noted in the letter. The is should review and determine whether terminating that ward will have a structural impact on the scientific outcome originally intended by the IC and act as appropriate on the remaining awards.
- **Diversity Tables** – Ignore and issue the grant using the term provided above.
- **Diversity Plans** – Ignore and issue the award using the term provided above.

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Appendix 3 – Language provided to NIH by HHS providing examples for research activities that NIH no longer supports. Use this language for HHS terminations only.

- 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 since 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.
- 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.
- COVID: 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.


Appendix 5 – Notice of Funding Opportunity (NOFO) Guidance
[pending]
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Appendix 6 – Frequently Asked Questions

1. **When reviewing applications for activities that are no longer an NIH/HHS priority/authority, should ICs review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICs do not need to review Other Support for alignment with NIH/HHS priorities/authority.

2. **For phased awards where the second phase (i.e., Type 4) will not be awarded due to NIH/HHS priority/authority, how should the IC notify the recipient that the Type 4 will not be issued?**

   OPERA is following up on this question, and will provide additional guidance, when available.

3. **When revising awards to terminate a project, how should the IC respond to red bars in SEAR?**

   The IC should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICs can clear the SEAR flag with a comment that the project is being terminated.

4. **If a project is terminated on an HHS list or a Type 5 is withheld because the project is no longer an NIH/HHS priority/authority, can the IC issue a subsequent Type 2 award?**

   No. If a project has been terminated due to agency priorities, it is no longer eligible for a renewal award.

5. **For recipients of K awards that are terminated due to NIH/HHS priority/authority, will eligibility requirements be modified to allow the individual to apply for another K award?**

   OER is reviewing this policy and will provide additional guidance, when available.

6. **When ICs issue revised NOAs to terminate awards, do they have to use the exact language provided by HHS in the termination term?**

   Yes, ICs must use the exact language provided in Appendix 3, with no edits.

EXHIBIT 11



NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH 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.

TABLE OF CONTENTS

1 GLOSSARY **I-1**
1.1 Abbreviations **I-1**
1.2 Definition of Terms **I-7**
2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION **I-44**
2.1 Roles and Responsibilities **I-44**
2.1.1 NIH and HHS Staff I-44
2.1.2 Recipient Staff I-45
2.2 eRA Commons **I-47**
2.2.1 eRA Commons Registration I-47
2.2.1.1 eRA Commons Registration for the Organization I-48
2.2.1.2 eRA Commons Registration for the PD/PI I-48
2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Application and Research Performance Progress Reports I-49
2.3 Application Information and Processes **I-49**
2.3.1 Support Mechanisms I-49
2.3.2 Eligibility I-50
2.3.3 Types of Award Instruments I-50
2.3.4 Types of Applications I-50
2.3.5 Types of Notices of Funding Opportunities (NOFOs) I-51
2.3.5.1 Other Funding-Related Notices I-53
2.3.6 Legal Implications of Applications I-53
2.3.7 Policies Affecting Applications I-54
2.3.7.1 Direct Cost Limitations for Applications That Include Consortium/Contractual F&A Costs I-54
2.3.7.2 Requirements for Submitting Unsolicited Applications Requesting $500,000 or More in Direct Costs I-54
2.3.7.3 Resubmission of Unfunded RFA Applications I-55
2.3.7.4 Resubmission of an Unfunded Application I-55
2.3.7.5 New Investigators and Early Stage Investigators I-56
2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance I-56
2.3.7.7 Post-Submission Grant Application Materials I-57
2.3.7.8 SAM Registration and Unique Entity Identifier (UEI) Requirements I-60
2.3.7.9 Graduate Student Compensation I-61
2.3.7.10 NIH Data Management and Sharing and Genomic Data Sharing I-62
2.3.7.11 Human Fetal Tissue from elective abortions I-62
2.3.7.12 Biographical Sketches (Biosketches) I-62
2.3.8 Application Forms I-62
2.3.9 Application Receipt Information and Deadlines I-63
2.3.9.1 Electronic Submission Requirements I-63
2.3.9.2 Late Applications I-64
2.3.9.3 Continuous Submission for Appointed Members of NIH Federal Advisory Committees I-64
2.3.9.4 Similar, Essentially Identical, or Identical Applications I-65
2.3.9.5 Application Non-conformity I-65
2.3.9.6 Natural Disasters and Other Emergencies I-66
2.3.10 Fraud, Waste and Abuse of NIH Grant Funds I-66

2.3.11 Availability and Confidentiality of Information I-68
2.3.11.1 Availability of Information I-68
2.3.11.2 Confidentiality of Information I-68
2.3.12 Protecting Sensitive Data and Information Used in Research I-71
2.4 The Peer Review Process I-71
2.4.1 Initial Review I-71
2.4.1.1 Responsibilities I-71
2.4.1.2 Overall Impact I-72
2.4.1.3 Scored Review Criteria I-72
2.4.1.4 Additional Review Criteria I-73
2.4.1.5 Additional Review Considerations I-73
2.4.2 Appeals of Initial Scientific Review I-74
2.4.3 National Advisory Council or Board Review I-75
2.4.4 Disposition of Applications I-76
2.5 Completing the Pre-Award Process I-77
2.5.1 Just-in-Time Procedures I-77
2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement I-80
2.5.3 Determining Applicant Organization Eligibility I-80
2.5.4 Determining Eligibility of Individuals I-81
2.5.5 Cost Analysis and Assessment of Management Systems I-82
3 OVERVIEW OF TERMS AND CONDITIONS IIA-1
3.1 Federalwide Standard Terms and Conditions for Research Grants IIA-2
4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES IIA-3
4.1 Public Policy Requirements and Objectives IIA-3
4.1.1 Animal Welfare Requirements IIA-10
4.1.1.1 Animal Welfare Assurance Requirements IIA-11
4.1.1.2 Verification of IACUC Approval IIA-12
4.1.1.3 Consortiums IIA-12
4.1.1.4 Foreign Recipients and Foreign Performance Sites IIA-13
4.1.1.5 Reporting to OLAW IIA-13
4.1.2 Civil Rights Protections IIA-14
4.1.2.1 Civil Rights Act of 1964 ..... IIA-14
4.1.2.2 Educational Amendments of 1972 ..... IIA-14
4.1.2.3 Rehabilitation Act of 1973 ..... IIA-14
4.1.2.4 Age Discrimination Act of 1975 ..... IIA-15
4.1.2.5 Limited English Proficiency IIA-15
4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement IIA-15
4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information IIA-15
4.1.3.2 Food and Drug Administration Amendments Act (FDAAA) IIA-17
4.1.3.3 Good Cause Extension (GCE) Request Requirements IIA-17
4.1.4 Confidentiality IIA-19
4.1.4.1 Certificates of Confidentiality IIA-19
4.1.4.2 Confidentiality of Alcohol and Substance Use Patient Records IIA-21
4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act IIA-21
4.1.5 Controlled Substances IIA-21
4.1.6 Debarment and Suspension IIA-21

4.1.7 Drug-Free Workplace IIA-23
4.1.8 Federal Funding Accountability and Transparency Act (FFATA) IIA-23
4.1.9 Federal Information Security Management Act IIA-24
4.1.10 Financial Conflict of Interest IIA-24
4.1.11 Fly America Act IIA-27
4.1.12 Health and Safety Regulations and Guidelines IIA-28
4.1.13 Human Stem Cell Research IIA-28
4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding IIA-29
4.1.14 Human Fetal Tissue Research IIA-29
4.1.14.1 Research on Transplantation of Human Fetal Tissue IIA-30
4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions IIA-31
4.1.15 Human Subjects Protections IIA-32
4.1.15.1 Federalwide Assurance Requirements IIA-34
4.1.15.2 Certification of IRB Approval IIA-35
4.1.15.3 Reporting to Funding Agency and OHRP IIA-36
4.1.15.4 OHRP Oversight IIA-36
4.1.15.5 Education in the Protection of Human Research Participants IIA-36
4.1.15.6 Data and Safety Monitoring IIA-36
4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects IIA-37
4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation IIA-38
4.1.15.9 Good Clinical Practice Training for NIH Recipients Involved in NIH-funded Clinical Trials IIA-39
4.1.15.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research IIA-40
4.1.16 Investigational New Drug Applications/Investigational Device Exceptions IIA-40
4.1.17 Lobbying Prohibition IIA-41
4.1.18 Metric System IIA-42
4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education IIA-42
4.1.20 National Environmental Policy Act IIA-42
4.1.21 Nondelinquency on Federal Debt IIA-43
4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program IIA-43
4.1.22.1 PEPFAR Agreements IIA-43
4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non-Governmental Organizations (NGOs) IIA-44
4.1.23 Pro-Children Act of 1994 ..... IIA-45
4.1.24 Public Health Security IIA-46
4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents) IIA-46
4.1.24.1.1.1 Select Agent Awards to U.S. Institutions IIA-46
4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and International Organizations IIA-46
4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents IIA-47
4.1.24.2 Dual Use Research of Concern IIA-47

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention IIA-48
4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees IIA-48
4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules IIA-49
4.1.26.1 Scope and Availability IIA-49
4.1.26.2 Institutional Biosafety Committee IIA-49
4.1.26.3 Investigators and Institutional Staff IIA-50
4.1.27 Research Misconduct IIA-50
4.1.28 Seat Belt Use IIA-51
4.1.29 Smoke-Free Workplace IIA-52
4.1.30 Standards of Conduct IIA-52
4.1.31 Text Messaging While Driving IIA-52
4.1.32 Trafficking in Persons IIA-53
4.1.33 USA Patriot Act IIA-53
4.1.34 Responsibility/Qualification Information in SAM.gov IIA-53
4.1.35 Mandatory Disclosures IIA-54
4.1.36 Never Contract with the Enemy IIA-54
4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment IIA-55
4.2 Appropriation Mandates IIA-55
4.2.1 Acknowledgment of Federal Funding IIA-55
4.2.2 Dissemination of False or Deliberately Misleading Information IIA-56
4.2.3 Gun Control IIA-56
4.2.4 Human Embryo Research and Cloning Ban IIA-56
4.2.5 Lobbying—Appropriation Prohibition IIA-56
4.2.6 Promotion or Legalization of Controlled Substances IIA-57
4.2.7 Restriction on Abortion Funding IIA-57
4.2.8.1 Exceptions to Restrictions on Abortions IIA-57
4.2.9 Restriction on Distribution of Sterile Needles IIA-57
4.2.10 Salary Cap/Salary Limitation IIA-58
4.2.10 Restriction of Pornography on Computer Networks IIA-58
4.2.11 Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates IIA-58
5 THE NOTICE OF AWARD IIA-59
5.1 Notice of Award Notification IIA-61
5.2 Associated Applications and/or Awards IIA-61
5.3 Funding IIA-61
5.4 Budget IIA-62
5.5 Additional Terms and Conditions IIA-63
6 PAYMENT IIA-64
6.1 Smartlink II/ACH IIA-64
6.2 Cash Request IIA-64
6.3 Interest Earned on Advances of Grant Funds IIA-65
6.4 Improper Payments Elimination and Recovery Improvement Act IIA-65
7 COST CONSIDERATION IIA-66
7.1 General IIA-66
7.2 The Cost Principles IIA-66
7.3 Direct Costs and Facilities and Administrative Costs IIA-67

7.4 Reimbursement of Facilities and Administrative Costs IIA-68
7.5 Cost Transfers, Overruns, and Accelerated and Delayed Expenditures IIA-71
7.6 Allocation of Costs and Closely Related Work IIA-72
7.7 Applicable Credits IIA-72
7.8 Services Provided by Affiliated Organizations IIA-72
7.9 Allowability of Costs/Activities IIA-73
7.9.1 Selected Items of Cost IIA-74
8 ADMINISTRATIVE REQUIREMENTS IIA-103
8.1 Changes in Project and Budget IIA-103
8.1.1 NIH Standard Terms of Award IIA-103
8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period IIA-104
8.1.1.2 Cost-Related Prior Approvals IIA-105
8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds IIA-106
8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement IIA-107
8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff IIA-107
8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs IIA-107
8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions. IIA-107
8.1.2 Prior Approval Requirements IIA-107
8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension IIA-109
8.1.2.2 Alterations and Renovations IIA-109
8.1.2.3 Capital Expenditures IIA-109
8.1.2.4 Carryover of Unobligated Balances IIA-109
8.1.2.5 Change in Scope IIA-110
8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA IIA-112
8.1.2.7 Change of Recipient Organization IIA-113
8.1.2.8 Change in Recipient Organizational Status IIA-117
8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA IIA-118
8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organization IIA-118
8.1.2.11 Provide Subawards Based on Fixed Amounts IIA-119
8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Project Period IIA-119
8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period IIA-120
8.1.2.14 Pre-Award Costs IIA-120
8.1.2.15 Rebudgeting of Funds from Trainee Costs IIA-120
8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work IIA-120
8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued IIA-120
8.1.3 Requests for Prior Approval IIA-121
8.2 Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources IIA-121

8.2.1 Rights in Data (Publication and Copyrighting) IIA-122
8.2.2 NIH Public Access Policy IIA-123
8.2.3 Sharing Research Resources IIA-123
8.2.3.1 Policy for Data Management and Sharing (DMS Policy) IIA-124
8.2.3.2 Genomic Data Sharing (GDS) Policy IIA-126
8.2.3.3 Sharing Model Organisms IIA-126
8.2.4 Inventions and Patents IIA-127
8.2.5 Interim Research Products IIA-135
8.3 Management Systems and Procedures IIA-136
8.3.1 Financial Management System Standards IIA-136
8.3.2 Program Income IIA-137
8.3.2.1 Reporting Program Income IIA-137
8.3.2.2 Sale of Real Property, Equipment, and Supplies IIA-138
8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents IIA-139
8.3.3 Property Management System Standards IIA-139
8.3.3.1 Real Property IIA-140
8.3.3.2 Equipment and Supplies IIA-140
8.3.4 Procurement System Standards and Requirements IIA-142
8.3.4.1 General IIA-142
8.3.4.2 Approval Requirements IIA-142
8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises IIA-143
8.3.4.4 Domestic Preferences for Procurements IIA-143
8.4 Monitoring IIA-143
8.4.1 Reporting IIA-144
8.4.1.1 Non-Competing Continuation Progress Reports IIA-144
8.4.1.2 Streamlined Non-Competing Award Process IIA-145
8.4.1.3 Progress Reports for Multiyear Funded Awards IIA-147
8.4.1.4 Final Research Performance Progress Report (F-RPPR) IIA-147
8.4.1.5 Financial Reports IIA-147
8.4.1.6 Invention Reporting IIA-150
8.4.1.7 Financial Conflict of Interest Reports IIA-150
8.4.1.8 NIH Disclosure Requirements IIA-151
8.4.2 Record Retention and Access IIA-151
8.4.3 Audit IIA-152
8.5 Specific Award Conditions and remedies for noncompliance (specific award conditions and Enforcement Actions) IIA-154
8.5.1 Specific Award Conditions: Modification of the Terms of Award IIA-155
8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support IIA-155
8.5.3 Other Enforcement Actions IIA-157
8.5.4 Recovery of Funds IIA-157
8.5.5 Debt Collection IIA-157
8.6 Closeout IIA-158
8.6.1 Final Federal Financial Report IIA-158
8.6.2 Final Research Performance Progress Report IIA-159
8.6.3 Final Invention Statement and Certification IIA-159
8.6.4 Submission of Closeout Documents IIA-159
8.7 Grant Appeals Procedures IIA-160

9 MULTIPLE PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR APPLICATIONS AND AWARDS IIB-2
9.1 General IIB-2
9.2 Applicability IIB-2
9.3 Application Requirements IIB-2
9.4 Application Review and Award IIB-4
9.5 Post-Award Administration IIB-4
10 CONSTRUCTION, MODERNIZATION, OR MAJOR ALTERATION AND RENOVATION OF RESEARCH FACILITIES IIB-6
10.1 General IIB-6
10.1.1 Eligibility IIB-7
10.1.2 Notices of Funding Opportunity IIB-7
10.1.3 Application Review and Award IIB-7
10.1.4 Title to Site IIB-8
10.1.5 Matching Requirement IIB-8
10.2 Procurement Requirements for Construction Services IIB-9
10.2.1 General IIB-9
10.2.2 Liquidated Damages IIB-10
10.3 Contracting Methods IIB-10
10.3.1 Design-Bid-Build IIB-10
10.3.2 Alternate Contracting Methods IIB-10
10.3.2.1 Construction Manager IIB-10
10.3.2.2 Design-Build Services IIB-11
10.3.2.3 Guaranteed Maximum Price IIB-12
10.4 Design Documentation Requirements IIB-12
10.4.1 Minimum Design Requirements for Construction, Modernization and Major A&R IIB-13
10.5 Equal Opportunity and Labor Standards IIB-13
10.5.1 Equal Employment Opportunity IIB-14
10.5.2 Nonsegregated Facilities IIB-14
10.5.3 Labor Standards IIB-14
10.5.3.1 Contract Work Hours and Safety Standards IIB-14
10.5.3.2 Disposition of Unclaimed Wages IIB-15
10.6 Real Property Management Standards IIB-15
10.6.1 General IIB-15
10.6.2 Notice of Federal Interest IIB-16
10.6.3 Insurance Requirements IIB-16
10.6.4 Use of Facility and Disposition IIB-17
10.6.5 Real Estate Appraisals IIB-18
10.7 Allowable and Unallowable Costs and Activities IIB-18
10.8 Administrative Requirements IIB-20
10.8.1 Prior Approval Requirements IIB-20
10.8.2 Alteration and Renovation Projects Under Non-construction Grants IIB-21
10.9 Closeout IIB-22
10.10 Public Policy Requirements IIB-23
10.10.1 Executive Orders IIB-26
11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS IIB-31
11.1 General IIB-31

11.1.1 Background IIB-31
11.1.2 Nondiscrimination IIB-31
11.2 Individual Fellowships IIB-31
11.2.1 General IIB-31
11.2.2 Eligibility IIB-32
11.2.2.1 Research Areas IIB-32
11.2.2.2 Research Training Program IIB-32
11.2.2.3 Degree Requirements IIB-32
11.2.2.4 Citizenship IIB-33
11.2.2.5 Sponsorship IIB-33
11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows) IIB-34
11.2.2.7 Individuals on Active Military Duty IIB-34
11.2.3 Application Requirements and Due Dates IIB-35
11.2.3.1 Application IIB-35
11.2.3.2 eRA Commons Registration IIB-35
11.2.3.3 ORCID iDs IIB-35
11.2.3.4 Letters of Reference IIB-35
11.2.3.5 Responsible Conduct of Research IIB-36
11.2.3.6 Concurrent Applications IIB-38
11.2.3.7 Receipt Dates IIB-38
11.2.4 Review IIB-38
11.2.4.1 Overall Impact IIB-38
11.2.4.2 Scored Review Criteria IIB-38
11.2.4.3 Additional Review Criteria IIB-39
11.2.4.4 Additional Review Considerations IIB-39
11.2.4.5 Secondary Level of Review IIB-39
11.2.5 Notification of Action IIB-39
11.2.6 Period of Support IIB-40
11.2.7 Full-Time and Part-Time Training IIB-41
11.2.8 Initiation of Support IIB-41
11.2.8.1 Process IIB-41
11.2.8.2 Payment IIB-42
11.2.9 Allowable and Unallowable Costs IIB-42
11.2.9.1 Pre-award Costs IIB-42
11.2.9.2 Stipends IIB-42
11.2.9.3 Stipend Levels IIB-43
11.2.9.4 Institutional Allowance IIB-43
11.2.9.5 Tuition and Fees IIB-44
11.2.9.6 Travel to Foreign Training Sites IIB-45
11.2.9.7 Childcare Costs IIB-45
11.2.9.8 Employee Benefits IIB-45
11.2.9.9 Rebudgeting of Funds IIB-46
11.2.10 Supplementation of Stipends, Compensation, and Other Income IIB-46
11.2.10.1 Stipend Supplementation IIB-46
11.2.10.2 Compensation IIB-46
11.2.10.3 Other Income: Concurrent Benefits IIB-47
11.2.10.4 Other Income: Educational Loans or GI Bill IIB-47
11.2.10.5 Other Income: NIH Loan Repayment Program IIB-47
11.2.10.6 Taxability of Stipends IIB-47
11.2.10.7 Form 1099 ..... IIB-47
11.2.11 Reporting Requirements IIB-48

11.2.11.1 Activation Notice IIB-48
11.2.11.2 Payback Agreement IIB-48
11.2.11.3 Termination Notice IIB-48
11.2.11.4 Consecutive Support IIB-49
11.2.11.5 Progress Reports IIB-49
11.2.11.6 Financial Reporting IIB-49
11.2.12 Changes in the Project IIB-49
11.2.13 Other Terms and Conditions IIB-50
11.2.13.1 Leave IIB-50
11.2.13.2 Termination IIB-51
11.2.13.3 Publications and Sharing of Research Results IIB-51
11.2.13.4 Copyright IIB-51
11.2.13.5 Inventions and Patents IIB-51
11.2.13.6 Disposition of Professional Fees IIB-52
11.2.13.7 Public Policy Requirements and Objectives IIB-52
11.2.13.8 Applicability of NIH Standard Terms of Award IIB-53
11.3 Institutional Research Training Grants IIB-53
11.3.1 General IIB-53
11.3.2 Eligibility IIB-53
11.3.2.1 Applicant Eligibility IIB-53
11.3.2.2 Research Areas IIB-53
11.3.2.3 Training Program Director/Principal Investigator(s) IIB-54
11.3.2.4 Research Training Program IIB-54
11.3.2.5 Degree Requirements IIB-55
11.3.2.6 Citizenship IIB-56
11.3.3 Application Requirements and Due Dates IIB-57
11.3.3.1 Application IIB-57
11.3.3.2 Due Dates IIB-57
11.3.3.3 Special Program Considerations IIB-57
11.3.3.4 Recruitment Plan to Enhance Diversity IIB-58
11.3.3.5 Training in the Responsible Conduct of Research IIB-61
11.3.4 Review IIB-63
11.3.4.1 Overall IIB-63
11.3.4.2 Overall Impact IIB-63
11.3.4.3 Scored Review Criteria IIB-63
11.3.4.4 Additional Review Criteria IIB-63
11.3.4.5 Additional Review Considerations IIB-64
11.3.4.6 National Advisory Council Review IIB-64
11.3.5 Notification of Action IIB-64
11.3.6 Period of Support IIB-64
11.3.6.1 Training Grants IIB-64
11.3.6.2 Trainees IIB-64
11.3.6.3 Kirschstein-NRSA Limitations IIB-65
11.3.7 Initiation of Support IIB-66
11.3.8 Allowable and Unallowable Costs IIB-66
11.3.8.1 Pre-Award Costs IIB-66
11.3.8.2 Stipends IIB-67
11.3.8.3 Trainee Tuition and Fees IIB-67
11.3.8.4 Training-Related Expenses IIB-68
11.3.8.5 Trainee Travel Costs IIB-68
11.3.8.6 Short-Term Training Costs IIB-69

11.3.8.7 Employee Benefits IIB-69
11.3.8.8 Facilities and Administrative Costs IIB-69
11.3.9 Rebudgeting of Funds IIB-69
11.3.10 Stipend Supplementation, Compensation, and Other Income IIB-70
11.3.10.1 Stipend Supplementation IIB-70
11.3.10.2 Compensation IIB-70
11.3.10.3 Other Income: Concurrent Benefits IIB-70
11.3.10.4 Other Income: Educational Loans or GI Bill IIB-71
11.3.10.5 Other Income: NIH Loan Repayment Program IIB-71
11.3.10.6 Taxability of Stipends IIB-71
11.3.10.7 Form 1099 ..... IIB-71
11.3.11 Carryover Authority IIB-71
11.3.12 Program Income IIB-72
11.3.13 Reporting Requirements IIB-72
11.3.13.1 Statement of Appointment (Form PHS 2271) IIB-72
11.3.13.2 Payback Agreement (Form PHS 6031) IIB-73
11.3.13.3 Termination Notice (Form PHS 416-7) IIB-73
11.3.13.4 Research Performance Progress Reports IIB-73
11.3.13.5 Federal Financial Report (FFR) IIB-73
11.3.14 Closeout IIB-74
11.3.15 Changes in the Project IIB-74
11.3.16 Other Terms and Conditions IIB-74
11.3.16.1 Leave IIB-74
11.3.16.2 Termination IIB-75
11.3.16.3 Publications and Sharing of Research Results IIB-75
11.3.16.4 Copyright IIB-76
11.3.16.5 Inventions and Patents IIB-76
11.3.16.6 Disposition of Professional Fees IIB-76
11.3.16.7 Public Policy Requirements and Objectives IIB-76
11.4 Payback Requirements IIB-77
11.4.1 General IIB-77
11.4.2 Implementation IIB-77
11.4.3 Payback IIB-78
11.4.3.1 Service Payback IIB-78
11.4.3.2 Financial Payback IIB-79
11.4.3.3 Extensions of Payback IIB-80
11.4.3.4 Waiver IIB-81
11.4.4 Certification of Payback Activities IIB-81
11.4.4.1 Annual Payback Activities Certification (Form PHS 6031-1) IIB-81
11.4.4.2 Annual Certification IIB-81
11.4.4.3 Change of Address IIB-82
11.4.4.4 Breaks in Kirschstein-NRSA Support IIB-82
11.4.4.5 National Health Service Corps IIB-82
12 RESEARCH CAREER DEVELOPMENT ("K") AWARDS IIB-83
12.1 General IIB-83
12.1.1 Background IIB-83
12.2 Types of Career Development Awards IIB-83
12.2.1 General IIB-83
12.2.2 Individual Mentored Career Development Awards IIB-83
12.2.2.1 Mentor IIB-84

12.2.3 Career Transition Awards IIB-84
12.2.3.1 K22 ..... IIB-84
12.2.3.2 Pathway to Independence Award (K99/R00) IIB-84
12.2.4 Individual Non-mentored (Independent) Career Development Awards IIB-86
12.2.5 Institutional Scientist Development Programs IIB-86
12.3 Eligibility IIB-86
12.3.1 Eligible Institutions IIB-87
12.3.2 Eligible Individuals IIB-87
12.3.3 Degree Requirements IIB-87
12.3.4 Citizenship IIB-87
12.3.5 Type of Appointment IIB-88
12.3.5.1 Temporary Adjustments to the Full-Time Institutional Appointment Requirement IIB-88
12.3.6 Level of Effort IIB-89
12.3.6.1 Mentored CDAs IIB-89
12.3.6.2 Concurrent Support IIB-90
12.3.6.3 Non-mentored CDAs IIB-91
12.3.6.4 Temporary Adjustments to the Percent Effort Requirement IIB-91
12.3.7 Prior Research Support IIB-92
12.4 Application Requirements and Due Dates IIB-92
12.4.1 Application IIB-92
12.4.1.1 Letters of Reference IIB-93
12.4.1.2 Concurrent Applications IIB-93
12.4.1.3 Environment and Institutional Commitment to the Candidate IIB-93
12.4.1.4 Training in the Responsible Conduct of Research IIB-94
12.4.1.5 Budget IIB-95
12.4.1.6 Submission Dates IIB-96
12.5 Review IIB-96
12.5.1 Overall Impact IIB-96
12.5.2 Scored Review Criteria IIB-96
12.5.3 Additional Review Criteria IIB-97
12.5.4 Additional Review Considerations IIB-97
12.6 Notification of Action IIB-97
12.7 Period of Support IIB-97
12.8 Allowable and Unallowable Costs IIB-98
12.8.1 Salaries and Fringe Benefits IIB-98
12.8.2 Research Development Support Costs IIB-99
12.8.3 Proposal Preparation Costs IIB-99
12.8.4 Facilities and Administrative Costs IIB-99
12.9 Rebudgeting of Funds IIB-99
12.10 Carryover Authority IIB-99
12.11 Reporting Requirements IIB-100
12.11.1 Progress Reports IIB-100
12.11.2 Federal Financial Report IIB-100
12.11.3 Closeout IIB-100
12.11.4 Post Closeout Evaluation IIB-100
12.12 Changes in the Project IIB-100
12.12.1 Temporary Off-Site Career Development Experience IIB-101
12.13 Other Terms and Conditions IIB-101
12.13.1 Leave IIB-101

12.13.1.1 Unpaid Leave IIB-102
12.13.2 Statement of Appointment—Institutional CDAs Only IIB-102
12.13.3 Early Termination IIB-102
12.13.4 Other Income: Generation and Disposition of Professional Fees IIB-103
13 MODULAR APPLICATIONS AND AWARDS IIB-104
13.1 General IIB-104
13.2 Applicability IIB-104
13.3 Application Requirements IIB-104
13.3.1 Budget IIB-104
13.4 Application Review and Award IIB-105
13.5 Post-Award Administration IIB-105
14 SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS) IIB-106
14.1 General IIB-106
14.2 Applicability IIB-106
14.3 Definitions IIB-106
14.4 Eligibility IIB-107
14.5 Application Requirements IIB-107
14.6 Public Policy Requirements and Objectives IIB-107
14.6.1 The United States Hotel and Motel Fire Safety Act of 1990 ..... IIB-107
14.6.2 Guideline on the Inclusion of Underrepresented Populations IIB-107
14.6.3 Plans to Promote Safe Environments at Conferences IIB-108
14.7 Application Review IIB-109
14.8 Funding IIB-109
14.9 Acknowledgment of Funding Source and Disclaimer IIB-110
14.10 Allowable and Unallowable Costs IIB-110
14.10.1 Allowable Costs IIB-110
14.10.2 Unallowable Costs IIB-111
14.11 Administrative Requirements IIB-112
14.11.1 Intellectual Property: Publications, Copyright, and Public Disclosure IIB-112
14.11.2 Reporting and Record Retention IIB-112
14.11.2.1 Progress/Final Report IIB-112
14.11.2.2 Federal Financial Report IIB-113
15 CONSORTIUM AGREEMENTS IIB-114
15.1 General IIB-114
15.2 Administrative and Other Requirements IIB-115
15.2.1 Written Agreement IIB-115
15.2.2 Public Policy Requirements and Objectives IIB-117
15.2.3 Allowable and Unallowable Costs IIB-118
15.2.4 Approval Authorities IIB-118
15.2.5 Tangible Personal Property IIB-118
15.2.5.1 Exempt Property IIB-118
15.2.5.2 Nonexempt Property IIB-118
15.2.6 Audit IIB-119
16 GRANTS TO FOREIGN ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS IIB-120
16.1 General IIB-120
16.2 Eligibility IIB-120

16.3 Application Review **IIB-121**
16.4 Public Policy Requirements and Objectives **IIB-121**
16.5 Funding and Payment **IIB-122**
16.6 Allowable and Unallowable Costs **IIB-123**
16.7 Administrative Requirements **IIB-123**
16.7.1 Changes in Project and Budget IIB-124
16.7.2 Change in Scope IIB-124
16.7.3 Change of Recipient Organization IIB-124
16.7.4 Audit IIB-124
16.7.5 Reporting and Record Retention IIB-124
17 GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO FEDERAL EMPLOYEES UNDER GRANTS **IIB-125**
17.1 General **IIB-125**
17.2 Eligibility **IIB-125**
17.3 VA-University Affiliations **IIB-125**
17.4 Public Policy Requirements and Objectives **IIB-126**
17.5 Payment **IIB-126**
17.6 Allowable and Unallowable Costs **IIB-126**
17.7 Administrative Requirements **IIB-129**
17.7.1 Equipment Accountability IIB-129
17.7.2 Procurement Requirements IIB-129
17.7.3 Intellectual Property IIB-129
17.7.4 Reporting Requirements IIB-129
18 GRANTS TO FOR-PROFIT ORGANIZATIONS **IIB-130**
18.1 General **IIB-130**
18.2 Eligibility **IIB-130**
18.3 Allowable and Unallowable Costs **IIB-130**
18.3.1 Cost Principles IIB-130
18.3.2 Facilities and Administrative Costs (Indirect Costs) IIB-130
18.3.3 Profit or Fee IIB-130
18.4 Administrative Requirements **IIB-130**
18.4.1 Equipment Accountability IIB-131
18.4.2 Intellectual Property IIB-131
18.4.3 Program Income IIB-131
18.4.4 Operating Authorities IIB-131
18.4.5 Audit IIB-131
18.4.6 Labor Distribution Requirements for For-Profit Organizations IIB-132
18.5 Small Business Innovation Research and Small Business Technology Transfer Programs **IIB-132**
18.5.1 NIH Fast-Track Application Process IIB-134
18.5.2 Eligibility IIB-134
18.5.2.1 Place of Performance IIB-136
18.5.2.2 Change in Organization Size & Change of Recipient Institution Actions IIB-136
18.5.2.3 Minimum Level of Effort IIB-137
18.5.2.4 Multiple Program Director/Principal Investigator Applications and Awards IIB-137
18.5.3 Public Policy Requirements and Objectives IIB-138
18.5.4 Allowable Costs and Fee IIB-138

18.5.4.1 Program Levels (Total Costs) IIB-138
18.5.4.2 Profit or Fee IIB-138
18.5.4.3 Facilities and Administrative Costs (Indirect Costs) IIB-139
18.5.5 Administrative Requirements IIB-139
18.5.5.1 Market Research IIB-139
18.5.5.2 Intellectual Property IIB-140
18.5.5.3 Data Sharing IIB-143
18.5.5.4 SBIR Life Cycle Certification IIB-143
18.5.5.5 STTR Life Cycle Certification IIB-145
18.5.5.6 Final RPPR IIB-147
18.5.5.7 Phase II Data Collection Requirement for Government SBIR Reporting Database IIB-147

19 RESEARCH PATIENT CARE COSTS IIB-149

19.1 General IIB-149
19.2 Definitions IIB-149
19.3 Policy IIB-150
19.4 Allowable Costs IIB-150
19.4.1 Computing Research Patient Care Costs IIB-151
19.4.2 Facilities and Administrative Costs IIB-151
19.4.3 Special Procedures for Certain Hospitals IIB-151
19.4.3.1 Recipients IIB-151
19.4.3.2 Consortium Participants/Contractors under Grants IIB-152
19.4.4 Financial Responsibilities IIB-152
19.5 Program Requirements IIB-152
19.6 Post-Award Requirements IIB-153

20 INSTITUTES AND CENTERS III-1

20.1 Other NIH Offices III-5
20.2 Other HHS Government Offices III-10

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.

2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

NIH is the steward of medical and behavioral research for the Nation. Its mission 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. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations,for-profit organizations, and individuals). NIH also works closely with other HHS components and other Federal departments and agencies. HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, ACL, OASH, and CMS, among others.

The rules that govern grants and cooperative agreements detailed at 2 CFR Part 200, and in certain cases further codified through HHS regulation, provide the framework for the terms and conditions of NIH awards, as specified in "Part II: Terms and Conditions of NIH Grant Awards" on page IIA-1.

NIH is organized into ICs, which have their own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in Part III. Although the ICs operate under the same general grant process and requirements, applicants and recipients need to be aware of differences that may exist. This information may be obtained from NIH IC staff. The policies generally applicable to NIH grants are set forth in the NIHGPS.

2.1 ROLES AND RESPONSIBILITIES

NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and recipient staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the recipient. The responsibilities of CSR and IC staff members, who are involved only in the initial review phase of the peer review process, are described in The Peer Review Process—Initial Review—Responsibilities. The responsibilities of other offices, such as OHRP, are described in Part II as applicable.

2.1.1 NIH and HHS Staff

The roles and responsibilities of NIH and HHS participants are as follows:

- ***Grants Management Officer.*** The GMO whose name appears in the NoA is the NIH official responsible for the business management and other non-programmatic aspects of the award. 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 applicants and recipients, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO works closely with their counterparts in other NIH ICs and with the designated PO. The GMO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award. A Chief Grants Management Officer is the principal GMO who provides leadership to an organizational component that is responsible for the business and fiscal management of the ICs grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
- ***Grants Management Specialist.*** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.
- ***Program Official.*** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team on many of these activities.
- ***Scientific Review Officer.*** SROs are health science administrators who manage the activities of SRGs, including CSR study sections. The SRO is responsible for conduct of the SRG in accordance with applicable laws, regulations, and policies. For the SRG for which they are responsible, the SRO reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, manages conflicts of interest and confidentiality, and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting.
- ***Other NIH, HHS and Federal Agency Staff.*** In addition to the GMO and PO, the recipient may be required to interact with other NIH or HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating F&A costs and research patient care rates, typically the cognizant CAS office, ONR, or DFAS; OIG; OHRP; ORI; OLAW; and OPERA. Staff members in these offices generally coordinate with the GMO, but they are responsible for discrete areas of specialization and are not required to channel their communications with the recipient through the GMO. Part III includes a list of these organizations and their addresses and telephone numbers. ONR is the cognizant agency for negotiation of F&A costs for some NIH recipients.

2.1.2 Recipient Staff

Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI (s), the AOR, and the Research Administrator. As key members of the grant team, they respectively lead the scientific and administrative aspects of the grant. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only

with the designated PD/PI(s) and AORs. The roles and responsibilities of recipient participants are as follows:

- ***Authorized Organization Representative***. The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar grant application. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see Legal Implications of Applications.) This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the recipient organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.
- ***Program Director/Principal Investigator.*** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one identified PD/PI on an application diminishes neither the responsibility nor the accountability of any individual PD/PI.

  When a single PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

  When multiple PD/PIs are designated, NIH requires identification of one PD/PI who will be designated as the Contact PD/PI. This person is responsible for communication between the PD/PIs and NIH. 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. They are not required to be an employee of the applicant organization. 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. This same principle applies to all PD/PIs at the applicant organization; e.g., they need not be employees; however, the applicant organization must have a formal written agreement in place.

When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role. For additional information, see NIHGPS Section 9 Multiple Program Director/Principal Investigator Applications and Awards.

PD/PIs are members of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO/GMS concerning the business and administrative aspects of the award. The NIH staff contacts list includes contact information for NIH grants management and program staff at each IC.

- ***Research Administrator***. The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

2.2 ERA COMMONS

eRA Commons is an online interface where grant applicants, recipients and Federal staff at NIH and grantor agencies can conduct their research administration business electronically as well as access and share administrative information relating to research grants. While applicants use Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the NIH grant administration process. Following application submission, the eRA Commons becomes the primary site for accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of notification of extensions without funds, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the recipient organization.

2.2.1 eRA Commons Registration

An organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

2.2.1.1 eRA Commons Registration for the Organization

Prospective applicant organizations should also see Legal Implications of Applications before beginning the eRA Commons registration process.

Organizations may verify their current registration status by running the "Commons Registered Organizations" query. This query can be run without logging into the Commons. The resulting list includes organization name and location and the NIH-assigned IPF Code that has been stored in the institutional profile for that organization.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the Register in eRA Commons page.

Once an organization is registered, information in the Institutional Profile can be maintained through the Commons.

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization's registration in the Commons does not mean an organization is an acceptable recipient for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process. See Determining Applicant Organization Eligibility for additional information.

Foundations that represent already existing recipient organizations, or a newly formed consortium where the consortium members are already individually recognized as NIH recipient organizations present unique and complex situations and should contact the Systems Policy Branch, OPERA before attempting to separately register as a new applicant organization.

2.2.1.2 eRA Commons Registration for the PD/PI

The individual(s) designated as the PD/PI(s) on the application must also be registered in the Commons. The PD/PI(s) must hold a PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization**. However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in their personal profile.

Designating the PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., summary statements, scores, electronic submission status, etc.). The PI role within the eRA Commons is necessary to complete the grant application process, to view the impact score and summary statement (the SO role also has this capability), and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

For more information on the features of the eRA Commons, including links to resources such as user guides and frequently asked questions, see the eRA Commons webpage.

2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Application and Research Performance Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in a NIH-funded project for at least one person month or more should also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular research grant, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular research grant, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

When an individual is assigned the Undergraduate, Graduate Student, 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. The Commons user name ID for those with an Undergraduate, Graduate Student, or Postdoctoral Role is not required at the time of application submission, but will be required as part of the Research Performance Progress Report (RPPR).

For individuals at the postdoctoral level, this requirement is already in effect and progress reports will not be accepted if the Commons ID is not provided. For individuals at the undergraduate and graduate student levels, a Commons ID is required with RPPRs. The Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now.

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.

In addition to the above roles, a Commons ID is required at the time of submission for sponsors in fellowship applications, component leads on multi-project applications, candidates for support under Research Supplements to Promote Diversity in Health-Related Research (Diversity Supplements), and primary mentors on career development applications. A Commons ID is also required at the time of application submission for all individuals listed on the R & R Senior / Key Person Profile (Expanded) Form; the requirement applies to Senior/Key Personnel as defined in NIHGPS Section 1.2 as well as Other Significant Contributors (OSCs). For other roles 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.

2.3 APPLICATION INFORMATION AND PROCESSES

This section provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, legal implications of applications, policies affecting application preparation and submission, application forms, application receipt information and deadlines, fraud, waste and abuse of NIH grant funds, and availability and confidentiality of application information.

2.3.1 Support Mechanisms

NIH ICs award grants under multiple programs and subprogram initiatives and use a variety of support mechanisms. NIH grants may be distinguished by purpose, type of recipient, amount, or other

characteristics. One method NIH uses to differentiate the various support mechanisms is an activity coding that indicates the category and specific form of support (e.g., R01, F32, P01, R43). The applicability of requirements may vary for different activity codes. Some of the distinctions also are significant for purposes of applying Part II. NIH ICs may vary in the way they use specific activity codes; not all ICs accept applications for all types of grant programs and may apply specialized eligibility criteria. See a comprehensive list of activity codes on NIH's web site.

2.3.2 Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals (see Completing the Pre-Award Process—Determining Applicant Organization Eligibility). Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the NOIFO, program guidelines, or other publicly available documents. Part IIB includes information on fellow and trainee eligibility.

2.3.3 Types of Award Instruments

NIH uses several different extramural award instruments in support of its mission. The Federal Grant and Cooperative Agreement Act of 1977 (P.L. 95-224) distinguishes financial assiance between contracts, cooperative agreements and grants. The NIHGPS requirements requirements apply to grants and cooperative agreements. Both grants and cooperative agreements are financial assistance instruments.

The grant instrument is used to administer awards that do not require NIH involvement beyond standard agency monitoring and stewardship. Under a cooperative agreement, NIH expects to be substantially involved in carrying out the project. Grants are used both for investigator-initiated research and for more targeted research. Cooperative agreements generally do not result from investigator-initiated applications. However, NIH may apply terms and conditions that differ from those in the NIHGPS consistent with the nature of its involvement under cooperative agreements.

2.3.4 Types of Applications

In the NIH grants process, five types of applications are used most frequently. The first four application types described below are considered “competing” because, through the peer review process, the application must compete for available funding with other applications.

- ***New Application (Type 1).*** A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.
- ***Renewal (Type 2).*** A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.

- ***Revision (Type 3).*** A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period. A revision application must have the same title as the currently funded grant. (A Type 3 prefix also refers to a request/award for a non-competing administrative supplement [see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Need for Additional NIH Funding without Extension of Budget and Project Period.]).
- ***Resubmission (suffix -A1).*** An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. A resubmission application may be submitted for any of the three preceding types of applications provided an appropriate NOFO is available. See Application Information and Processes—Policies Affecting Applications for other policies affecting Resubmissions. NIH allows only one resubmission application.
- ***Non-Competing Continuation Progress Report (Type 5).*** A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

In addition to the list above, NIH periodically uses a pre-application (also known as a "white paper" or "précis") to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity. Pre-applications are generally used in combination with a competing application in a 2-phase process. Pre-applications do not result in an award; the end result is the opportunity to submit to the subsequent phase of a particular program. Successful applicants to the pre-application phase are notified of the opportunity to submit to the subsequent phase. In addition to the pre-application, NIH may use an application process for prospective applicants to request access to an NIH research resource. This process also does not result in an award; the end result is permission to access a resource. NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards (e.g., 5R0198765-02 is a non-competing continuation progress report).

2.3.5 Types of Notices of Funding Opportunities (NOFOs)

Most applications submitted to NIH under the categories of research and research training (including fellowships) are investigator-initiated. NIH accepts applications on the application due dates noted on the submission schedule. NIH generally reviews applications in three review cycles per year; however any variations in schedule will be noted in the NOFO. Some ICs review applications for Institutional National Research Service Awards (T32) only once a year; such information is generally found in a particular NOFO. The schedules for submission, review, and award of investigator-initiated applications are available on the NIH standard due dates web page.

Notice of Notice of Funding Opportunity (NOFO). In accordance with 2 CFR 200.204, NOFO is an umbrella term for a publicly available document in which NIH makes known its intentions to award "Discretionary Award" on page I-19, usually as a result of competition for funds.Each NOFO includes a solicitation identifie, will outline the program goals and objectives, and will include information to allow prospective applicants to determine whether the entity is eligible to apply. All applications must be electronically submitted in response to a NOFO.

NIH NOFOs primarily fall into the categories of Program Announcements, (PAs), which include Parent Announcements, and Requests for Applications (RFAs). While individual announcements will continue to carry an announcement number reference to PA or RFA, all announcements are NOFOs. NOFO is the general term is used to reference any type of funding announcement. NIH uses the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

- ***Parent Announcement.*** Electronic submission of applications requires that applications must be associated with a specific NOFO. Therefore, NIH omnibusbroad parent announcements are provided for applicants to submit investigator-initiated (unsolicited) applications. Responding to such an omnibus or umbrella parent NOFO ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. This process in no way diminishes the interest of NIH ICs in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some ICs may limit their participation; therefore, prospective applicants should check the announcement to determine IC participation. For institute-specific opportunities in a particular area of science, search the *NIH Guide for Grants and Contracts*.
- ***Program Announcement (PA).*** A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through PARs (PAs with special receipt, referral, and/or review considerations) and PASs (PAs with set-aside funds).

ICOs issuing PARs or PASs may now choose to describe within the NOFO criteria that would make an application non-responsive to the PAR/PAS. Only applications to PARs and PASs that include non-responsive criteria will be evaluated by the ICOs upon receipt for non-responsiveness. These non-responsive criteria will be listed in the Funding Opportunity Description section (Part 2, Section 1). Those applications that are deemed non-responsive will be withdrawn from review.

PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated. PAs also are used to annually solicit applications for the SBIR and STTR programs. Those applications must be received by the dates specified in the PA.

- ***Request for Applications (RFA).*** An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and recipients as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by an SRG specially convened by the awarding component that issued the RFA.

All applications involving one or more clinical trials must be submitted through a NOFO specifically designed for clinical trials. NIH will not process applications that propose one or more clinical trials if the NOFO (Part 2, Section 2) indicates clinical trials are “Not Allowed.” Applications that propose clinical trials, including applications with a mix of trial and non-trial aims or a combination of clinical and non-clinical studies, must be submitted to NOFOs designated as clinical trial “Optional” or “Required".

All NIH NOFOs are published in the *NIH Guide for Grants and Contracts* and on Grants.gov under Search Grants (https://www.grants.gov/web/grants/search-grants.html). NIH may develop areas of high

priority or special research interest and use a special announcement to stimulate submission of applications in those areas. These NOFOs are also published in the *NIH Guide for Grants and Contracts*.

2.3.5.1 Other Funding-Related Notices

Notice of Intent to Publish (NOITP). The purpose of an NOITP is to alert the extramural research community of an upcoming funding opportunity.

Request for Information (RFI). The purpose of an RFI is to alert the extramural research community to a request for comments on a specific issue. A RFI does not include reminders, extensions, or clarifications to RFIs.

2.3.6 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOR's signature further certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application. 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.

Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization's behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. The applicant also is expected to be in compliance with applicable State and local laws and ordinances.

Applicants may be required to provide proof of organizational eligibility (such as proof of non-profit status), trainee or fellow eligibility and citizenship, or other eligibility information. Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research; and research involving live vertebrate animals. Part II details public policy requirements and cost and administrative policies.

Affiliate organizations and other similar administrative organizations

There are times when an institution desires to use an affiliate organization, such as a Foundation or other similar organization to provide administrative services for NIH grants. These situations are often complex and each situation is unique when determining which organization is the appropriate applicant institution. Foundations, particularly those associated with institutions already recognized as NIH recipient organizations, should contact the Division of Grants Systems Integration, OPERA before attempting to separately register as an applicant organization.

Similarly, when new consortiums are formed where the consortium members are already separately recognized as NIH recipient organizations, DGSI/OPERA should be contacted before attempting to

separately register as a new applicant organization. See NIHGPS Section 7.8 Services Provided by Affiliated Organizations.

2.3.7 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. This section describes NIH policies that affect application preparation and/or submission. Specific details on application content are addressed in application instructions and specific NOFOs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

2.3.7.1 Direct Cost Limitations for Applications That Include Consortium/Contractual F&A Costs

For NOFOs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation. This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting $250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit; however, they may be requested in addition to the $250,000.

This policy also impacts applications requesting a budget of $500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific NOFO that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs.

2.3.7.2 Requirements for Submitting Unsolicited Applications Requesting $500,000 or More in Direct Costs

Any applicant requesting $500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks or as specified in the NOFO before submission for prior approval. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting the $500,000 threshold in the aggregate even if no single application in the group requests that much.

This policy does not apply to applications submitted in response to RFAs or to other announcements that include specific budgetary limits. However, any such application must be responsive to budgetary limits

specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a cover letter to that effect with the name of the authorizing program staff member and IC affiliation (see The Peer Review Process). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless a particular NOFO states that resubmissions from an RFA may be submitted, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes and do not mention prior review anywhere in the application (including the cover letter). In these cases the reviewers will not be provided with the previous summary statement.

2.3.7.4 Resubmission of an Unfunded Application

An unfunded competing application (A0) may be resubmitted for future funding opportunities. These applications are referred to as a resubmission application (A1). NIH will only accept a single resubmission (A1) application. NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application or a prior A0 application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review. NIH's policy for accepting overlapping applications remains in effect: NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that NIH will not review:

1. 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.
2. a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
3. an application that has substantial overlap with another application pending appeal of initial peer review (see Section 2.3.9.4 below)

NIH policy allows a 37 month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision

application constitutes the starting point for the 37 month policy. After 37 months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the 37 month period.

Submission to a different NOFO under review at the same time is not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See Resubmission of Unfunded RFA Applications above). The new application must be submitted on the scheduled due dates for new applications. It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

New Investigator. In general, a PD/PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial NIH independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

Early Stage Investigator (ESI). An ESI is a New Investigator who has completed their terminal research degree or end of post-graduate clinical training (i.e., completing medical residency, whichever is later, within the past 10 years at the time of application submission and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award. Extensions of the end of ESI eligibility date may be requested following the procedures documented on the Early Stage Investigator Extensions page on the NIH Grants & Funding website. Please note an investigator will retain their ESI status if they receive smaller research grants, training, infrastructure, and career awards appearing on this list.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and ESI status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the eRA Commons profile for the individual.

2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or

fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

For individual Fellowship applications, this assurance requirement applies to the individual fellow and the sponsor. Such an assurance must include at least the follow certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the Fellow has read the Ruth L. Kirschstein National Research Service Award Payback and will abide by the Assurance if an award is made; and (5) that the award will not support residency training. 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 the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

2.3.7.7 Post-Submission Grant Application Materials

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

Allowable Post-Submission Materials for All Applications

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Citations of issued patents
- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Special submission procedures are required for videos.

- Other post-submission materials specified in the NOFO for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application, which must include only**:
    - List of authors and institutional affiliations
    - Title of the article
    - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Notice of Funding Opportunity (NOFO) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Preliminary Data NIH will accept preliminary data as post-submission material for Type 1 R01, R21, or R03 applications, including resubmissions, if the NOFO used for submission allows preliminary data in the application.

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news—since the training grant application was submitted—of:

- A trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- A faculty member's promotion, funding, or publications; and
- The addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).
- Lists of publications for Training Grant are allowed. Follow the page limits in the NIH Table of Page Limits.

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively, the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the NOFO for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organ- izational officials, the AOR must send the materials directly to the SRO or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a copy to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment, except for video submissions. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check their application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Non-traditional Application Materials

NIH will accept only videos as non-traditional application materials. No devices or other media will be accepted unless specified in the Notice of Funding Opportunity (NOFO). However, videos may include demonstrations of devices and other items as listed below. These guidelines may be superseded by instructions in specific NOFOs.

The only acceptable content for videos is demonstrations of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time; or demonstrates movement or change.

- Examples of acceptable content include unusual interventions or surgical procedures, prototype model use, visualization of 3-D structures or structural changes in molecules or cells, software or database demonstrations, educational materials or video games.
- Examples of unacceptable content include virtual tours of laboratories, equipment in place, platform presentations, advertisements, commercials, or PowerPoint presentations [unless requested by the Scientific Review Officer (SRO) in lieu of a site visit].

Application requirements. Videos may only be submitted as post-submission materials and not embedded in or linked from the application materials unless expressly instructed to do so in the funding opportunity instructions.The application must be structured at the time of submission to indicate that a video will be submitted subsequently. The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted. Key images/“stills” and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.

When human subjects or personally identifiable information is represented in a video, the applicant organization is responsible for ensuring that human subjects have been consented and protected appropriately. Submission through the Authorized Organizational Representative (AOR) certifies acceptance of this responsibility.

Video formats. Multiple videos may be submitted per application but their aggregate length must not exceed 2 minutes for single-project applications and 5 minutes for multi-component applications.

Post-submission videos can be submitted as an mp4, mov, avi, or wmv video format with a maximum file size of 25 MB. This material can be submitted via e-mail and it will be uploaded to the grant folder by the SRO.

Closed captioning is not required when narration is present. However, captioning is recommended as an optional component of the video to assist reviewers evaluating the application.

Limitations. Video files containing unacceptable content or exceeding the time or size limits will not be accepted. Applications submitted with hyperlinks to videos or with videos embedded in the research strategy will be considered in violation of page limits and the application will be withdrawn before review.

Additional information on post-submission videos can be found on the NIH Format Attachments webpage.

Note: Due to technological constraints, the NIH cannot guarantee that reviewers will be able to view videos.

Video submission. If the submission requirements have been met (see above), videos will be accepted by the SRO managing the review. After the assignment of the application to a review group is visible in the eRA Commons, the applicant should contact the SRO for that review group to discuss logistics for submission of any videos.

As with all other post-submission materials, videos must be received by the SRO one month (30 calendar days) prior to the peer review meeting or as otherwise specified in the NOFO. Videos will not be accepted if fewer than 30 calendar days remain before the peer review meeting.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the video may originate from the Program Director/Principal Investigator (PD/PI), Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a “cc” to the AOR will not be accepted.

The opportunity to submit additional materials should not be a means of circumventing submission deadlines, page limitations, or content requirements and should not substantially enhance, alter or add to the originally submitted application.

After the initial peer review phase is completed, the Chief GMO of the IC is the NIH official responsible for accepting additional materials. Most of the material submitted after peer review can be submitted as part of the Just-in-Time process.

2.3.7.8 SAM Registration and Unique Entity Identifier (UEI) Requirements

All applicant organizations must register in the System for Award Management (SAM), in accordance with Appendix I to 2 CFR Part 200(D.)(3.), and always maintain the registration with current information at all times during which such organizations have an application under consideration for funding by NIH and, if an award is made, until a final financial report is submitted or the final payment is received,

whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. SAM is the central repository for common government-wide certifications and representations required of NIH applicants and recipients. Additional information about registration procedures may be found at the SAM.gov internet site.

A Unique Entity Identifier (UEI) is issued as part of the SAM.gov registration process. The UEI must be provided on application forms; the same UEI must be used for all registrations, as well as on the grant application.

2.3.7.9 Graduate Student Compensation

The maximum amount NIH will award for the support of a graduate student on a research grant or cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend for postdoctoral fellows in effect at the time the grant award is issued on the Federal award date. Stipend levels are updated periodically in conjunction with an NIH annual appropriation and are published in the NIH Guide for Grants and Contracts. Consistent with cost principles for Institutions of Higher Education (IHEs) described in 2 CFR Part 200.431(j) and 200.466, the compensation of graduate students supported by research grants must be reasonable. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the recipient institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students. Expected future increases in NRSA stipends, to adjust for inflation, should permit annual increases in the maximum award for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, recipients are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH Institutes and Centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student com-

pensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

2.3.7.10 NIH Data Management and Sharing and Genomic Data Sharing

NIH issued the Data Management and Sharing (DMS) policy to promote the sharing of scientific data. Sharing scientific data accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies. Applicant projects that generate scientific data are subject to the DMS Ppolicy. Additionally, if applicable, genomic data sharing considerations must be submitted with the application. Please refer to Section 8.2.3.1 Policy for Data Management and Sharing (DMS Policy) for more information.

2.3.7.11 Human Fetal Tissue from elective abortions

For competing grant applications proposing the use of Human Fetal Tissue (HFT) from elective abortions 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 can be found in the application instructions and must be met within existing applicable page limits.

Applications that do not address all of the required information, including the detailed budget, will be administratively withdrawn and not reviewed.

2.3.7.12 Biographical Sketches (Biosketches)

NIH requires submission of a biographical sketch (also referred to as biosketch) for each proposed senior/key personnel and other significant contributor.

Applicants and recipients are required to submit biosketches in 1) competing applications for all types of grant programs; 2) in progress reports when new senior/key personnel or other significant contributors are identified; and 3) to support prior approval requests for changes in senior/key personnel status and changes of recipient organization.

NIH staff and peer reviewers utilize the biosketch to ensure that individuals included on the applications are equipped with the skills, knowledge, and resources necessary to carry out the proposed research. Applications containing one or more biosketches that do not conform to the required format may be withdrawn.

See the NIH Biosketch page for format pages, instructions and the NIH disclosure table.

2.3.8 Application Forms

Exhibit 3 lists the required application forms for competing applications, which vary by support mechanism. These forms and associated instructions are available on the NIH Forms and Format Pages..

Exhibit 3. Required Forms for Competing Applications

Application Title	Form Number	Use
SF424 (R&R) Application Guide for NIH and Other PHS Agencies	SF424 (R&R)	The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic submission.
SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ	SF424 (R&R) and PHS 416-1	The SF424 (R&R) form set, combined with a PHS Fellowship Supplemental form component, is used for electronic submission of individual fellowship applications. The PHS 416-1 may be used for e-mail form submissions of a change of sponsoring recipient organization application.
Application for a Public Health Service Grant	PHS 398	Form PHS 398 is used for paper submission for those programs that have not yet transitioned to electronic submission.

The NIH competing applications now require electronic application submission. Questions about application forms and instructions may be directed to DGSI/OPERA, OER, NIH; see Part III for contact information.

2.3.9 Application Receipt Information and Deadlines

The NIH generally requires electronic submission of all competing and administrative supplement applications. Applicants should carefully read instructions in the NOFO and the application guide to determine submission requirements. The NOFO will either provide unique application deadlines or refer to NIH's standard due dates.

NIH expects all applications to be submitted on time. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances and limited to two weeks past the due date. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Only DRR, CSR has the authority to accept a late application; however, contacting DRR in advance will not influence the acceptance of a late application. The NIH policy on late applications is stated in the applicable application instructions. Also see Late Applications below.

2.3.9.1 Electronic Submission Requirements

NIH requires electronic submission of:

• All competing (Type 1, Type 2) and administrative supplement (Type 3) applications;

• All Research Performance Progress Reports (RPPRs), including interim and final RPPRs (submitted electronically through the eRA Commons RPPR module);

• Change of recipient organization (Type 7) and successor-in-interest (Type 6) applications (may be submitted electronically via email).

All applications, regardless of the NOFO type, must be successfully submitted electronically to Grants.gov on or before 5:00 p.m. local time (of the applicant organization) on the appropriate date listed in the funding opportunity.

If an application due date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday, the due date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

Questions about application forms and instructions may be directed to DGSI/OPERA, OER, NIH; see Part III for contact information.

2.3.9.2 Late Applications

There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application (see details below). When the application due date falls on a weekend or Federal holiday, and is extended to the next business day, the window of consideration for late submission of applications will be calculated from that business day. Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in a cover letter submitted with the application.

Generally, when an applicant organization is closed due to natural disaster or other emergency situation, applications must include a cover letter indicating the reasons for the delay. In general, the delay should not exceed the time period that the applicant organization is closed, unless otherwise notified by the agency. Additional information can be found on the NIH Extramural Response to Natural Disasters and Other Emergencies webpage.

NIH will not consider accepting late applications under the following circumstances:

- Submissions to RFAs that must be reviewed on a compressed time line and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity”.
- Submissions to any NOFOs (RFAs, PAs, PARs, PASs) after the two-week window of consideration.

Please be aware that any reasons for late submission must be in relation to the individual(s) with the PD/PI role on the application. For multiple PD/PI (MPI) applications, the reasons may apply to any or all of the PD/PIs. This accommodation does not apply to co-Investigators, project leaders in a multi-component application, or other Key Persons listed in an application (unless they also have MPI status).

Examples of acceptable and unacceptable reasons for submission of a late application can be found in the NIH Submission Policies web page.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications.

Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral, Center for Scientific Review (CSR), NIH in advance will not influence the acceptance of a late application. Additional information on submission of electronic applications can be found in the applicable SF424 (R&R) Application Guide.

2.3.9.3 Continuous Submission for Appointed Members of NIH Federal Advisory Committees

Continuous Submission allows eligible members of NIH Federal Advisory Committees to submit applications for certain grant activity codes after the standard due date, until last day of the receipt period for each Advisory Council Round.

PD/PI individuals serving as appointed members of the following categories of NIH Federal Advisory Committees are eligible:

- Chartered NIHInitial/Integrated Review Groups (IRGs),
- NIH Boards of Scientific Counselors,
- NIH Advisory Boards or Councils,
- NIH Program Advisory Committees.

Eligibility begins on the date the appointment becomes active and continues for six weeks after the official date of retirement from appointed committee service. Thus, if retirement from appointed service occurs on June 30, continuous submission is permitted until August 16th of that year.

Continuous submission eligibility can be viewed in the reviewer's eRA Commons Personal Profile, in the Reviewer Information section.

eRA Commons users with account administration roles (e.g., SO – Signing Official, AO – Administrative Official, AA – Account Administrator, BO – Business Official) can check an investigator's eligibility using the Advanced Search feature in the Admin module.

Under Continuous Submission, applications received after the Advisory Council Round continuous submission period end dates will be assigned to the next Advisory Council Round, as described on the NIH Continuous Submission website. Please direct any continuous submission issues, including Grants.gov rejection messages, to the eRA Service Desk.

See NIH Continuous Submission website for details and procedures..

2.3.9.4 Similar, Essentially Identical, or Identical Applications

Simultaneous submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization for the same receipt date. This includes derivative or multiple applications that propose to develop a single product, process, or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted for the same receipt date. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed, or the application(s) may not be reviewed.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; or 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

2.3.9.5 Application Non-conformity

Applicants are reminded that non-conformity with application requirements can have serious consequences. NIH may withdraw any application identified during the receipt, referral and review process that does not conform with the instructions in the SF424 (R&R) Application Guide, the Notice of Funding Opportunity, and relevant NIH Guide Notices.

Some **examples** of how this policy is applied to NIH applications *include but are not limited to*:

- Applications containing biosketches that do not conform to the required format may be withdrawn.
- Applications that do not conform to the page limit requirements because inappropriate materials have been included in other parts of the application may be withdrawn.
- Applications submitted as new but containing elements of a resubmission or renewal application that do not conform with the resubmission policy and may be withdrawn.
- Applications submitted after 5 PM local (applicant organization) time on the application due date may be withdrawn.

It is important to remember that these are just examples, and that all requirements specified in the SF424 (R&R) Application Guide, the Notice of Funding Opportunity, and relevant NIH Guide Notices are to be followed. Questions about application requirements can be directed to NIH "Grants Info" or the Division of Receipt and Referral.

If an application is withdrawn because it does not conform to the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application.

2.3.9.6 Natural Disasters and Other Emergencies

For major disasters impacting many organizations, NIH will coordinate with other HHS components and Federal agencies (such as FEMA and OMB), as well as with state, local, and institutional representatives, to develop any additional response. NIH will consider such issues as whether a Federal Disaster is declared; the severity of damage inflicted; the length of time an organization may be required to close or that is required for recovery; the impact on investigators, human research subjects, and animal subjects; and the overall impact on the community.

Late applications due to natural disasters or other emergency situations are subject to the late application policy found in NIHGPS Section 2.3.9.2.1.

NIH responses to specific events will be issued in the form of an NIH Guide Notice published in the NIH Guide to Grants and Contracts.

2.3.10 Fraud, Waste and Abuse of NIH Grant Funds

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contact:

- Your institution’s Office of Sponsored Research, Compliance Office, or other responsible office,
- The NIH CGMO listed in the NoA for the IC that funded the grant,
- The DGCO/OPERA/OER.

In addition, allegations of criminal offenses should be reported to the Department of Health and Human Services, OIG Hotline.

The OIG has authority within HHS to conduct criminal investigations. The HHS OIG maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. The identity of the caller is kept confidential, and callers are not required to give their names. The address and telephone number of the OIG and the OIG hotline are included in Part III.

Further allegations of non-criminal misuse of grant funds, and recipient conflict of interest should be reported to the NIH OMA.

OMA provides a centralized management survey and review capability to promote program integrity, conducts appraisals of alleged incidents of waste, fraud, and abuse and has lead responsibility for cases received through the Office of Inspector General (OIG) Hotline that are referred to NIH for action. OMA has no authority to undertake criminal investigations. OMA refers all allegations of criminal offenses to the OIG for investigation. The address and telephone number for the OMA, DPI are included in Part III.

False statements involving falsified, fabricated, or plagiarized information identified during research misconduct proceedings should be reported to the NIH Extramural Research Integrity Officer.

Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of "ghost" individuals; charging inflated building rental fees for a building owned by the recipient; submitting false financial reports; and submitting false financial data in bids submitted to the recipient (for eventual payment under the grant).

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims. Part II includes administrative and other remedies the Federal government may use if a recipient deliberately withholds information or submits fraudulent information or does not comply with applicable requirements. Even if a grant is not awarded, the applicant may be subject to penalties if the information contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., provides for the administrative imposition by HHS of civil penalties and assessments against any person who knowingly makes false, fictitious, or fraudulent claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than $5,500 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to $150,000, may be made in lieu of damages. Regulations established by HHS at 45 CFR Part 79 specify the review process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287, and 18 U.S.C. 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States. Violations of these statutes carry a maximum sentence of five and eight years imprisonment, respectively.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A "claim" includes any request or demand for money or property made to the United States or to a contractor, recipient, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of $5,500 to $11,000 may be imposed for each false claim, plus damages of up to three times the amount of the damages the government sustains because of the violation, and the costs of any civil action brought to recover such penalties and damages.

NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 2 CFR Part 200.

2.3.11 Availability and Confidentiality of Information

2.3.11.1 Availability of Information

Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or recipient in the application or in the post-award phase is considered public information and, once an award is made, is subject to possible release to individuals or organizations outside NIH. The statutes and policies that require this information to be made public are intended to foster an open system of government and accountability for governmental programs and expenditures and, in the case of research, to provide information about federally funded activities.

NIH routinely places information about awarded grants, including project title, the name of the PD/PI, and the project description, on the RePORT Web site. For funded research grant applications, NIH also sends the project description provided by an applicant to the DoC's NTIS. NTIS disseminates scientific information for classification and program analysis. The public may obtain the project descriptions from RePORT or request them from NTIS. Other information may be released case by case as described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources and elsewhere in the NIHGPS.

2.3.11.2 Confidentiality of Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the application instructions.

When such information is included in the application, it is furnished to the Federal government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application (including the agreement by peer reviewers and Advisory Council members to the NIH confidentiality and nondisclosure rules); and the requirements of the FOIA and Privacy Act (5 U.S.C. 552 as discussed below). However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

2.3.11.2.1 Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR Part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect.

The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0225.

This system of record provides guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. It also includes requirements for safeguarding the records and for record retention and disposal.

Parties other than PD/PIs may request the release of Privacy Act grant records. Such requests are processed under FOIA. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than the subject of the file, NIH will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by recipients ordinarily are not subject to the requirements of 45 CFR Part 5b.

2.3.11.2.2 The Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR Part 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH. Generally, NIH cannot require recipients or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

NIH generally will release the following types of records pursuant to a FOIA request:

- Funded applications and funded progress reports, including award data.
- Final reports that have been transmitted to the recipient organization of any audit, survey, review, or evaluation of recipient performance.

NIH generally will withhold the following types of records or information in response to a FOIA request:

- Pending competing grant applications
- Unfunded new, renewal, and revision applications
- Financial information pertaining to project personnel, such as institutional base salary information
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
- Evaluative portions of site visit reports and peer review summary statements, including impact scores
- Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
- Information which, if released, would adversely affect the competitive position of the person or organization
- Patent or other valuable commercial rights of the person or organization

Applicants are instructed to identify proprietary information at the time of submission of an application. If, after receiving a FOIA request, NIH has substantial reason to believe that information in its records could reasonably be considered exempt from release, the appropriate NIH FOI office will notify the applicant or recipient, through the PD/PI, before the information is released. In the case of multiple PD/PI's the Contact PD/PI will be notified and is responsible for coordinating any response to the notice.

Multiple responses to the notice will not be accepted. If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA. The PD/PI will be given five (5) working days to identify potentially patentable or commercially valuable information that the PD/PI believes should not be disclosed. Any such submission must be specific as to the nature and type of commercial harm that will result if the requested information is released. Submissions that merely state in general terms that the grant application or portions should not be released will not be honored. If the PD/PI does not respond within that time period, the grant will be prepared for release in accordance with applicable FOIA policies and released to the requester. If the PD/PI does identify commercial or proprietary information an NIH official will review that response. After NIH consideration of the response, the PD/PI and recipient will be informed if NIH does not agree with the PD/PI's position. If a document contains both disclosable and non-disclosable information, the non-disclosable information will be redacted and the balance of the document will be disclosed.

The HHS regulations implementing FOIA provide that only the NIH FOI Officer may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are referred to the NIH FOI Officer along with written documentation of the rationale for nondisclosure. If the NIH FOI Officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media), HHS. Additional information on the FOIA process is available at the NIH FOI Office Web site.

2.3.11.2.3 Release of Research Data

NIH handles requests for the release of research data by certain types of recipients as FOIA requests. The term "research data" is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 2 CFR Part 200.315, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to for-profit organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the NIH scientific data sharing website. Additional information is available on the Data Management & Sharing Policy Overview web page. (Also see Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds have a vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, tablets, mobile devices, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also Public Policy Requirements and Objectives—Federal Information Security Management Act.

2.4 THE PEER REVIEW PROCESS

NIH policy is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias. Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act. The peer review system used by NIH, often referred to as the "dual review system," is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review for scientific merit by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various scientific and professional groups. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at NIH's web site or Peer Review Policies and Practices on the NIH Grants & Funding web site.

2.4.1 Initial Review

2.4.1.1 Responsibilities

The DRR in the CSR receives all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including NIH Research Enhancement Award applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of applications that have Institute-specific features such as conference grant applications, applications resulting from RFAs, and program project and center grant applications. CSR also may review other types of applications at an IC's request.

When the IC is responsible for the initial review, CSR reviews the application for completeness and staff in the soliciting IC review the application for responsiveness to the RFA/PAR/PAS, if applicable. The scientific review office in that IC coordinates the initial technical review for scientific merit and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These assignments are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that their application has been received and that they can find information about the application's SRO, SRG, and IC assignments in eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO, not the PO, is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR, and submitted to the SRO.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an impact score. Summary statements are then simultaneously provided to the IC's program staff, Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

The SRG assesses overall impact in the determination of scientific and technical merit; overall impact is defined based on the different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All the criteria, weighted as appropriate for each application or as described in the NOFO, will be considered when assigning the overall impact score.

2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, enhance health, and reduce illness and disability. For research grant applications, and most other types of applications, reviewers evaluate the overall impact to reflect their assessment of

the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the NOFO will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and determine a separate score for each. An application does not need to be strong in all categories to be evluated likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The NOFO should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Diversity Plan (for Conference Grant Applications)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan.
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and Reviewers should not consider these items in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The NOFO should be consulted for additional information describing each of the relevant additional review considerations.

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in NOFOs.

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the Notice of Funding Opportunity, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a “cc” to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at 42 CFR Part 52h.5 “Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects”, on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.

- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a "cc" to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Notice of Funding Opportunity when they are issued in the NIH Guide for Grants and Contracts.

2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter "Council") for use in the second level of

review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive $2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

All incomplete applications, non-compliant applications, and applications determined to be non-responsive to NOFO requirements will not be reviewed. If the NOFO remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. An application may resubmit one application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the NOFO allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

For complete, compliant and responsive applications, following the initial scientific peer review, the summary statement will be available to the PD/PI and AORs of the applicant organization with the Signing Official (SO) user role in the eRA Commons. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application, provided the NOFO allows resubmission applications. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application (referred to as a resubmission) for review in a future cycle.

Some of the ICs publish paylines as part of their funding strategies to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in Completing the Pre-Award Process below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify them of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each NOFO will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identify a hESC from the NIH Registry in the application.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or

human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH in accord with Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.

Other Support. Information on other active and pending support will be requested as part of the Just-in-Time procedures. Other support includes all resources made available to a researcher 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. This includes:

- Resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that is made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.
- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities and the activities fall outside of their appointment at the applicant or recipient institution.
- In-kind contributions, e.g., office/laboratory space, equipment, supplies, or employees or students supported by an outside source. If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

Other support does not include training awards, prizes, or gifts. Gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return. An item or service given with the expectation of an associated time commitment is not a gift and is instead an in-kind contribution and must be reported as Other Support.

Reporting of other support is required for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Each PD/PI or other senior/key personnel must electronically sign their respective Other Support form prior to submission. This signature certifies that the statements are true, complete, and accurate. Information on Other Support is not specifically requested for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application. It is also not requested for individuals categorized as Other Significant Contributors.

Recipients are expected to establish and maintain effective internal controls (e.g. policies and procedures) to ensure that individuals designated in applications as senior/key personnel fully disclose all Other Support information to their institution as soon as it becomes known. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

For Other Support submissions that include foreign activities and resources, recipients are required to submit copies of contracts, grants, or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation. If they are not in English, recipients must provide translated copies. This does not include personal service contracts, or employment contracts for fellows supported by foreign entities.

The supporting documentation must be provided as part of the Other Support PDF following the Other Support Format page. See NIH Other Support page for forms, instructions, and other resources.

IC scientific program and grants management staff will review this information before award to ensure the following:

- Sufficient levels of effort are committed to the project.
- There is no scientific, budgetary, or commitment overlap.
    - Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
    - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
    - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
    - Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.
- Only funds necessary for the approved project are included in the award.
- Any foreign resources that meet the definition of a foreign component have received appropriate prior approval.

See NIH Other Support for format page, instructions and the NIH disclosure table.

Certification of IRB Approval. If the proposed project involves human subjects research, a certification to NIH that all non-exempt research involving human subjects has been reviewed and approved by an appropriate IRB must be submitted. Pending or expired approvals are not acceptable. See Public Policy Requirements/Human Subjects for additional information.

Verification of IACUC Approval. If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. See Public Policy Requirements/Animal Welfare for additional information.

Human Subjects Research Education Requirement. If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.

Human Embryonic Stem Cells (hESCs). If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line (s) should be included in the Just-in-Time submission.

Genomic Data Sharing Institutional Certification. If the proposed project involves research subject to the Genomic Data Sharing policy for the generation of human genomic data (including within the Data Management and Sharing Plan, as applicable), investigators must submit an Institutional Certification,

or, in some cases, a Provisional Institutional Certification. Institutional certification forms and directions for completing them are available on the NIH GDS Data Sharing website. This certification must be submitted as a "Genome Data Sharing Certification" filein the eRA Commons Just-in-Time module.

SBIR Foreign Disclosure Form. For SBIR and STTR competing applications, applicants must submit the Required Disclosure of Foreign Affiliations or Relationships to Foreign Countries form. See NIH SBIR and STTR Foreign Disclosure requirements for more information. This form must be submitted as an "SBIR STTR Foreign Disclosure Form" file in the eRA Commons Just-in-Time module.

SBIR Funding Agreement Certification. For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://-grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

STTR Funding Agreement Certification. For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://-grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

My Bibliography Report of Publications. For renewal applicants to research training programs, a My Bibliography Report of Publications arising from work conducted by trainees while supported by the training grant will be collected in the Interim/Final Research Performance Progress Report.

Other Information Requested by the Awarding IC. NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animals sections of the application. If required, these changes must be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement

When requested by NIH as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with NIH PO and revise the Project Summary/Abstract, Specific Aims, and/or Public Health Relevance sections of their application as appropriate. Once all issues are resolved, applicants should e-mail a document with final versions of the revised sections to the IC-designated e-mail address (normally a Program Official, Grants Management Official, or centralized e-mail box) as a single Microsoft Word file only. Be reminded that all revised application information submitted to the NIH must be approved by an AOR. Applicants should use this template. The template includes specific headings that must be used for each section. All three headings must be included in the document that is submitted even if a particular section had no changes from the previous submission. If there are no changes for a section include the header but leave the text area blank to ensure appropriate processing of this information by NIH's electronic systems.

2.5.3 Determining Applicant Organization Eligibility

All applicant organizations must complete the one-time eRA Commons registration process (see NIHGPS 2.2.1 eRA Commons Registration) prior to submitting any application (paper or electronic) to the NIH. During the registration process, NIH may make a preliminary assessment of applicant organization eligibility. In an effort to streamline the registration requirements and reduce the administrative

burden (i.e., time between registration submission and NIH's final determination), NIH urges potential applicants to consider the following eligibility considerations:

- What is the nature of the research and business that your organization performs and how does that fit within the NIH mission?
- Is your organization professionally responsible for the research?
- How many people are in your organization?
- Are the researchers employed by your organization?
- Where will the proposed research physically be conducted?
- Can you identify a Notice of Funding Opportunity that you would apply for?
- Has your organization applied to and/or been directly funded by any other Federal agency?

Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH reserves the right to deny registration if an organization is determined not to be an appropriate applicant for a particular NOFO. 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 the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

NIH awards may be made only to eligible applicants. Continued funding is dependent on the recipient's continued eligibility. In general, domestic or foreign, public or private, non-profit or for-profit organizations and individuals are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be required to provide proof of its status by submitting documentation; otherwise, the AOR's signature on the application certifies that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing organizational eligibility, NIH may consider other factors relating to the applicant's ability to responsibly handle and account for Federal funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the PD/PI in the project, and the PD/PI's employment and citizenship status. Although some of these same considerations are reviewed as part of the peer review, NIH's concern at this stage in the process is making an award to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. NIH will not make an award to an applicant that does not have a substantive role in the project and would simply serve as a conduit for another entity.

2.5.4 Determining Eligibility of Individuals

It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The eligibility of these individuals to complete the project will be evaluated during peer review and at the IC level by grants management and program staff.

The GMO will verify whether the proposed PD/PI or other senior/key personnel are debarred or suspended from participation in Federal assistance programs (see Public Policy Requirements and Objectives—Debarment and Suspension for certification requirements).

Generally, PD/PIs and other personnel supported by NIH research grants are not required to hold any particular educational degree, and are not required to be U.S. citizens. However, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the NOFO. In these cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For example, under most career development awards or Kirschstein-NRSA individual fellowships, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award.

NIH requires the applicant to determine that individuals' visas will allow them to remain in this country long enough for them to be productive on the research project, but NIH does not provide guidance on or assess the different types of visas. NIH expects recipient organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, NIH may terminate the grant (see Administrative Requirements—Changes in Project and Budget and Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support).

The eligibility requirements for trainees and additional eligibility requirements for fellows are addressed in Ruth L. Kirschstein National Research Service Awards chapter in IIB.

In the post-award phase, NIH monitors changes in recipient and project status to ensure they meet legal and programmatic requirements and takes actions necessary to protect the Federal government's interests.

2.5.5 Cost Analysis and Assessment of Management Systems

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument and award mechanism, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the Cost Considerations chapter.

The amount of NIH funding is based on reasonable and allowable costs consistent with the principles of sound cost management, considering IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems that will support the expenditure of and accountability for NIH funds. When an applicant has had no prior Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior NIH or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other relevant available information to determine whether the applicant's management systems meet the standards established in 2 CFR Part 200. The GMO will advise the applicant if additional information is required. Based on the results of the review results, the GMO will determine the need for any corrective action and may impose specific award conditions on the award.

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 sub-awards/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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

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)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

(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-

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/26/2024 12:19 AM

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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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.)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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**

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/12/2024 12:06 AM

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.

Version:13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

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

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-

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

F&A Costs 1	$35,639

Version: 13 - 8/3/2022 12:59 PM | Generated on: 6/19/2023 12:05 AM

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)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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.

(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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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 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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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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:03 AM

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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

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.

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,

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

SECTION III – STANDARD TERMS AND CONDITIONS – 5R03MH130275-02

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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Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

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Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

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- 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/21/2024 12:32 AM

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

NIH National Institutes of Health
Office of Extramural Research

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.

[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

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

NIH National Institutes of Health
Office of Extramural Research

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.



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.

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 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

National Institutes of Health
Office of Extramural Research

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.

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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.

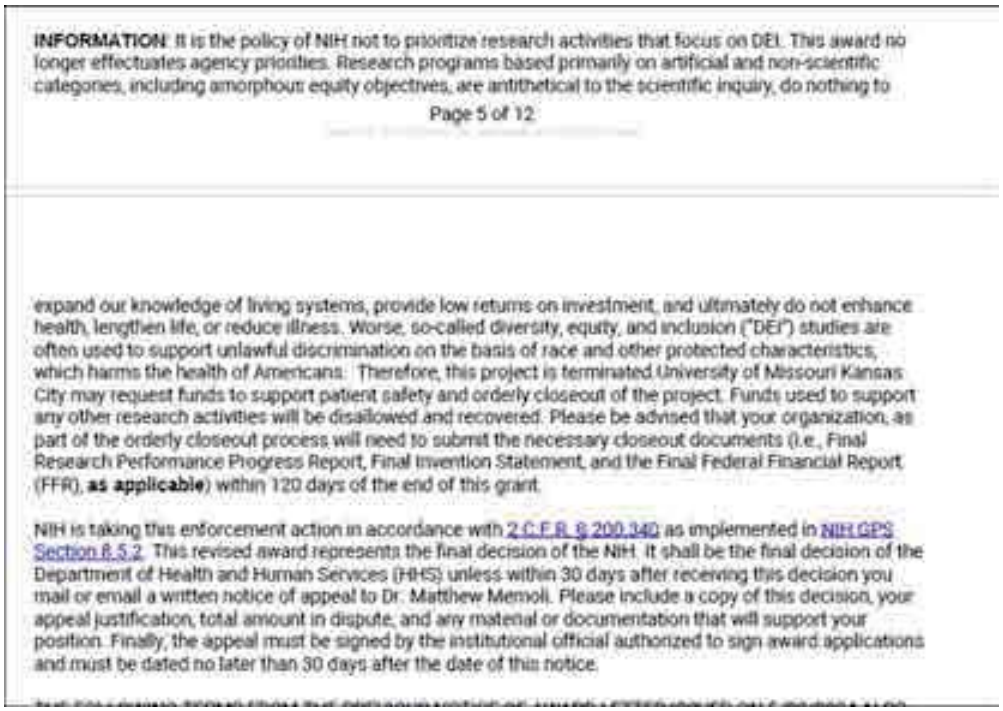
Delwyn

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





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

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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)

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

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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)

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: olumbia niversity SPA <s a@cumc.columbia.edu>
Sent: Saturday, March 22, 2025 :16 AM
To: ors @sfsu edu
Cc: olumbia niversity SPA grantrevie @columbia.edu Hughes, Tonda .
Subject: Im ortant Information regarding your Suba ard ith olumbia niversity

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

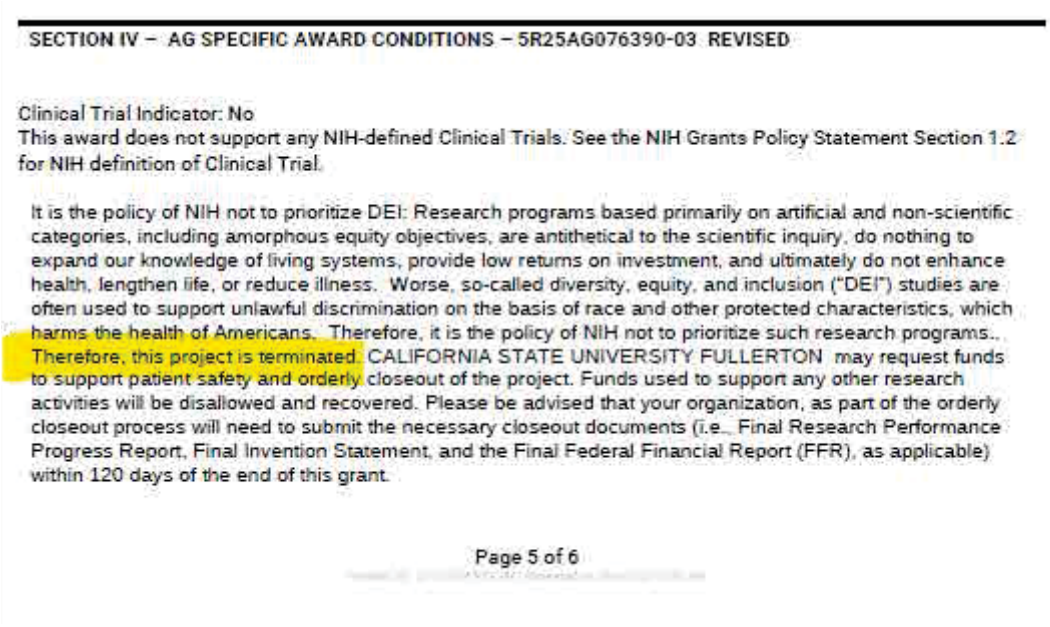
FW: [External] NoA: 5R25AG076390-03 PI: Jennifer Piazza

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: osen eig, ustin (NIH/NIGMS) [E] <rosen @nigms.nih.gov>
Sent: Thursday, March 2 , 2025 11:00 AM
To: aman Paul
Subject: Information regarding ISE a ard

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]

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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 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., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-10814

DECLARATION OF Vassilis L. Syrmos, Ph.D.

I, Vassilis L. Syrmos, 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 Vice President for Research and Innovation of the University of Hawai'i. I have personal knowledge of the facts set forth in this declaration, except to those matters stated upon information and belief; as to those matters, I believe them to be true. If required to testify, I 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 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 (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 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.

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 were to 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.

Reliance on NIH Funding

9. In the university's fiscal year 2024, the University of Hawai'i received direct funding obligations through the National Institutes of Health ("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 UH 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.

Typical Timeline and Processes for NIH Grant Awards

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.

Delays and Irregularities in the Processing of NIH Grant Applications

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. As of April 12, 2025, some NIH study sections have been scheduled, but the delays will impact timing and budgeting as noted below.

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 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.

Terminations of NIH Grants

27. Since March 21, 2025, the University of Hawai'i has had three NIH grants terminated, not including subawards from other NIH-funded institutions.

28. These terminations will result in the loss of approximately $403,000 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 of 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 three 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 terminations, 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 any updated "agency priorities" with which its research must align.

32. The three terminated grants, which are based at JABSOM and Cancer Center, 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.

(3) Cancer Center's "Longitudinal Study of Early NAFLD Progression and the Gut Microbiome in Asian Americans, Native Hawaiians and Whites" is a diversity supplement to the parent NIMHD grant. The study aims to provide evidence for the temporal relationship of the gut microbiome with the progression of non-alcoholic fatty liver disease (NAFLD) through population-based longitudinal studies. Findings may be used to inform novel targeted intervention strategies to prevent NAFLD progression and, ultimately, reduce liver cancer burden in multiple populations.

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. 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. However, upon information and belief, such bridge funding is temporary and in no way represents a sustainable solution. As of April 12, 2025, UH has implemented bridge funding of approximately $18,000 to cover the remainder of student payroll through the end of the academic year. Additionally, upon information and belief, $33,000 of departmental tuition funds are being used to support a faculty member and staff who previously received funding under a terminated grant. This prevents using these funds for any other purpose, including expanding the department's core instructional mission.

38. For currently funded awards where start-up funding or institutional support was committed, we will withhold future payments until there is more certainty on the awarding of already-appropriated funds (i.e., non-competitive renewal). We will likely 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. Upon information and belief, long-term use of non-federal funding is simply not a viable option. Upon information and belief, employee terminations will be necessary if federal funding does not materialize. The JABSOM has stopped recruitment for a permanent Associate Dean for Research. The funding uncertainties

have impacted offers for two clinical department chair searches, with both positions being critical for maintaining medical school accreditation. For other faculty recruitments in process, the delays and uncertainties of NIH funding limits our ability to offer start-up funding, which may result in those positions remaining unfilled.

39. As of April 12, 2025, JABSOM researchers, funded by 18 awards, are awaiting their notice of awards (NOAs) for budget periods that start April 1-May 1, 2025. This is well behind schedule of when these grants would typically be awarded, so, upon information and belief, JABSOM is facing the edge of a funding precipice. This tranche of awards includes two large infrastructure grants totaling about $13 million for the next budget year, will partially or fully employ more than 40 employees, including graduate students. Upon information and belief, use of alternative sources of funding for these employees is simply not a sustainable solution to replace delayed or lost funding of this magnitude. Major grants in "pending" status include the Centers of Biomedical Research Excellence (COBRE) Diabetes Phase II, which supports the Diabetes Research Center, which promotes basic science and translational research across the University of Hawai'i and at one of our largest affiliated health systems. People living in Hawai'i and the Pacific Islands have higher rates of pre-diabetes and diabetes compared to other populations living in the continental U.S. Additionally, Native Hawaiian and Pacific Islander populations have worse health outcomes from diabetes, including stroke and advanced heart disease. The other large grant pending its NOA is the Hawai'i IDeA Networks for Biomedical Research Excellence (INBRE), in its 23rd year of funding. The Hawai'i INBRE focuses on research training, career development, and enhancement of investigators, postdoctoral fellows, and undergraduate students of the R1 institution (University of Hawai'i at Mānoa), two primarily undergraduate institutions, and five community colleges across the state. This network

provides opportunities for advanced undergraduate student research experiences across institutions and supports a state-of-the-art Data Sciences core to provide cutting-edge services to our INBRE students and investigators at all stages of development. Importantly, the Hawai'i INBRE's Developmental Research Project Program for investigator support and development strengthens community college faculty members' capacity to conduct advanced research and mentor undergraduate students. Due to NIH delays, this INBRE program is currently being paid through an advance account, but payment in this manner or through other sources, upon information and belief, is not sustainable.

40. As of April 12, 2025, another 16 NIH awards, which include two large infrastructure grants, are awaiting review of their non-competitive renewal applications and receipt of their notice of award for the budget period starting June 1, 2025. This second tranche of NIH grants totals about $9 million for the next budget period and partially- or fully employs more than 80 people, including graduate students. Delays in or loss of this funding will jeopardize these positions, as there are currently no alternative sources to fund these positions sustainably, upon information and belief. One large infrastructure grant, the NIH Research Centers in Minority Institutions (RCMI) Specialized Center, Ola HAWAII, partners with other federally funded research and education programs across the University of Hawai'i at Mānoa to conduct biomedical (basic sciences), behavioral, and community-based research projects that target the highest priority health needs of medically underserved communities in Hawai'i. A major component of Ola HAWAII leverages other federally funded infrastructure grants to provide programmatic activities that enhance the career development of early-stage investigators, with an emphasis on enhancing their progress to become independent investigators. Faculty and post-doctoral fellows participate in these mentoring bootcamps, which include a unique focus on

health policy and community-based participatory research with Native Hawaiian, Pacific Islander, and Filipino communities. The diaspora of these populations spans the entire US and most of its territories. Hence, researchers from other states participate in this training since they lack the capacity to design research projects that can be maximally effective in these populations. Ola HAWAII funding fully or partially employs 67 people and provides subawards to experienced community partners and community principal investigators on O'ahu and Maui. The Pacific Center for Genome Research (PCGR) is the other large infrastructure grant in this tranche awaiting timely review of non-competitive renewal applications and receipt of the NOA before May 31, 2025. The PCGR aims to grow and support the genomic research workforce at the University of Hawai'i at Manoa, a goal that has been identified as a high priority in the state, including by the two largest health systems in Hawai'i. The PCGR activities enhance all career levels of undergraduate students, master's and PhD students, postdoctoral fellows, and junior faculty members. The INBRE and PCGR activities focus on undergraduate and graduate students through broad categories of science that improve understanding of chronic diseases that afflict millions across the US. The COBRE programs and Ola HAWAII focus on cardiovascular diseases (diabetes, heart disease, obesity) and other high-need, high-impact research topics by building the next generation of independent basic science, translational research, public health, nursing, and clinical researchers. These infrastructure grant programs further leverage federal and state dollars by actively contributing to large national networks of scientists whose work improves population health in their communities and contributes to scientific advances and a workforce that benefits all populations in the United States.

41. Additionally, a total of 28 faculty, early-stage investigators, staff, and ten graduate students are funded on indirect cost recovery accounts at JABSOM, totaling about

$835,000. These personnel include JABSOM's entire research administrative support office, some faculty and staff working to support shared services and cores that are critical to biomedical research across the University of Hawai'i at Mānoa, and projects developing improved undergraduate, graduate, and professional student support services. Such positions depend on continued NIH grant funding, as no viable alternative exists to fund these positions sustainably. Delays of or loss in funding jeopardizes such positions and programs that are critical to the University of Hawai'i at Mānoa as a whole.

42. As of April 12, 2025, Cancer Center researchers have seen delays and uncertainty concerning several NIH awards, including most significantly a grant renewal pending for a U54 application, Pacific Island Partnership for Cancer Health Equity (PIPCHE), that received a priority score. This grant renewal has a start date of September 1, 2025, and a total award in year 1 of $1,931,931, and $9,479,508 over five years, but, upon information and belief, the applicable Request for Applications (RFA) was taken down by NIH, which strongly evidences that this long-term grant is now coming to an end, or minimally that there will be delays that will lead to large and immediate funding shortfalls that the University of Hawai'i will not be able to cover for any sustainable period. Upon information and belief, the end of this more than twenty-year program will have catastrophic effects on the employment and prospects of the 35 Cancer Center faculty, staff, and graduate students supported by this grant and the populations served through this grant. Since 2003, the Cancer Center and the University of Guam (UOG) have worked in partnership through PIPCHE to explore the reasons behind significant cancer health disparities among Pacific Islanders in Hawai'i, Guam, and the neighboring U.S. Affiliated Pacific Islands (USAPI). This partnership is one of only 15 NCI-sponsored partnerships that support cancer research capacity building at minority-serving institutions and collaborative

research addressing cancer health disparities and their impact on underserved and socio-economically disadvantaged populations. The partnership addresses cancer health disparities through research, research education, and community outreach and engagement. Again, upon information and belief, there is no viable option to support these employees and the services they provide through other sources of funding on a long-term sustainable basis. Any bridge funding that might be provided to soften the landing of employees will not be a long-term solution.

Effect on Public-Facing or State-Supported Programs

43. The loss of the NIH RECOVER initiative impacts the comprehensive, coordinated care that 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.

44. Termination of JABSOM's pilot study "Evaluating HPV Vaccination Uptake Barriers and its Efficacy in PLWH" has severely impacted a population at high risk for significant illness caused by having HIV infection, which reduces the body's ability to clear the human papillomavirus (HPV), which is known to cause cancer of the cervical, anus, and posterior tonsils. Being unable to naturally kill the HPV virus places patients living with HIV at higher risk for developing HPV-related cancer. This research project was scheduled to recruit 50 men and women patients, conduct screening and biological sampling to determine what types of HPV patients have been exposed to, which identifies their risk level for developing cancer. Upon information and belief, this study is the main option for patients in Hawai‘i to find out if they are at high risk for developing anal cancer, and patients who participate in this study have access to

tests that are not available to patients in a clinical setting. Upon information and belief, there are no other options in a clinical setting in Hawai'i for this type of important screening and additional testing. Upon termination of the grant, the study was forced to shut down and cancel patient visits. Accordingly, individuals at very high risk for developing anal cancer are not receiving these critical screenings and additional testing, and, upon information and belief, as they have no other options available to them in Hawai'i, face a severe impact on their health.

Admissions, Training and Workforce Disruptions

45. The University of Hawai'i uses information regarding NIH grant applications and award rates to inform its admissions process at the graduate student level.

46. 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 fortermination (T34) or will not be renewed (MOSAIC K99/R00) at the end of this funding year. These training mechanisms are highly competitive and reviewed for scientific rigor, in the same manner as all NIH proposals. Notably, the Maximizing Access to Research Careers (MARC) program has also been terminated, with this to be the last funded year for all MARC grants across the country. At the University of Hawai'i, the MARC program funded a portion of the program staff, a graduate student, and six undergraduates in a two-year cohort, covering 60% of their tuition and a monthly stipend. As the MARC program is ending, these are concrete losses moving forward.

Loss of these training grants severely impacts the health and science workforce in our state, which suffers higher burdens of chronic diseases and environmental factors that increase the risk of developing chronic diseases.

47. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will continue to affect the research capabilities of the University of Hawai'i, including limiting the individuals qualified to conduct certain research. UH received notice that the highly competitive, high-value MOSAIC Pathways to Independence awards (MOSAIC K99/R00) is ending at the end of this funding period, and JABSOM has three such awards.

Concerns About FY25 Funds Being Obligated

48. 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.

49. 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.

50. 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

51. 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 despite the interim funding measures being taken

by UH to keep certain research going for now. UH has had to plan which of these valuable programs to continue with 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 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.

53. 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.

54. There is no way to make up for the lost time, the loss of research continuity, and the loss of training value for our current students.

Conclusion

55. 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 April 13, 2025 at Honolulu, HI.



Vassilis L. Syrmos, Ph.D.

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.

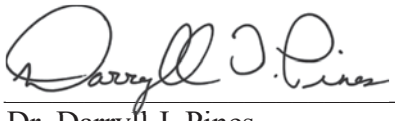
52. A new assistant professor in Biology had his first solo NIH grant submission cancelled when the Request for Applications was withdrawn. Two Professors in the Department of Cell Biology and Molecular Genetics have a fundable research project (R01) from the National Institute of Allergy and Infectious 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]



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

308472-00001

Notice of Award
FAIN# F32AA030194
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
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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:13 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:13 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:13 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:13 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:13 AM

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] | [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]

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).

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/25/2025 12:07 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/25/2025 12:07 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/25/2025 12:07 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/25/2025 12:07 AM

EXHIBIT 10

EXHIBIT 6. R01HD114134

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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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-

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:10 AM

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

’. Recipient Uni7ue Entity Identifier
KMH5K9V7S518

6. 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. Uni7ue 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

1’. Assistance Listing Program Title
Aging Research

16. 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
2’. Project Period Start Date 09/21/2023 **– End Date** 03/21/2025	
26. 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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 1R5' AG069510-01A1 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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

SUMMAR/ TOTALS FOR ALL / EARS (for this Document Number)		
/ R	**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 / ear: 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 – PA/ MENTY\HOTLINE INFORMATION – 1R5' AG069510-01A1 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 – 1R5' AG069510-01A1 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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 – 1R5' AG069510-01A1 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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 SUMMAR/
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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:03 AM

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 Preliminary Injunction.

Professional Background

3. I have been President of UMB 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 April 10, 2025, UMB has received notices of termination of 14 NIH awards.

28. The terminations received as of April 10, 2025 are attached as Exhibits 1-14.[1]

29. These terminations will result in the loss of more than $33.3 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.

h. 5T32GM144951-04: To address the lack of diversity in the science, technology, engineering, and math (STEM) workforce, this program aims to increase the participation of underrepresented minorities in biomedical Ph.D. programs, increase their retention rates, and provide career development to prepare students for a career in STEM. The program supported 5 first-year students with fellowships each year (15 total supported during first three years of award). In addition, the

program supported a community of students (55) who, while not on the fellowships, benefited from program activities, such as seminars.

i. 5R25GM113262-10: The project addresses urgent needs and demands for workforce and experiential diversity for creative problem solving of increasingly complex issues in biomedical research and healthcare. As part of the grant, the university, with its partners, administers 20 unique and interactive research training and mentoring programs that form a training continuum beginning at the 4th grade with UMB's Mini Medical School and continuing to the FIRST program, described below. The grant supported 5 students and multiple faculty and staff.

j. 1UC2CA293782-01: This project provides localized technical assistance and scientific support for community-led, health equity structural interventions with a goal of completing these interventions in a rigorous scientific manner and in a way that demonstrates how patients and researchers can collaborate to address social determinants of health and advance health equity in neighborhoods and society at large.

k. 5U54CA272205-03: In 2011, a Congressionally mandated National Academies report, Expanding Underrepresented Minority Participation: *America's Science and Technology Talent at the Crossroads*, recommended, among other things, the establishment of a program like NSF's ADVANCE program for underrepresented minorities in Science and Engineering. The NIH established the NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program to enhance and maintain cultures of inclusive excellence in the biomedical research community. Because evidence suggests that participation in the field of

biomedical research by individuals with a variety of lived experiences can help to alleviate healthcare disparities, this program created a comprehensive model to encourage outstanding individuals to enter the academic profession. Initial work toward this goal focused on hiring multiple cohorts of promising early-stage investigators who bring new perspectives to biomedical research by encouraging applications from a broad range of applicants with backgrounds and life experiences to bring new perspectives to biomedical research. The award was intended to support funding of 11 faculty, 7 of whom have been hired already.

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.

57. These terminated grants consisted of awards for which funding was to be distributed by the government for specific "projects" or areas of research and were competitively awarded based on the university's qualifications. UMB followed Federal processes as provided in the Federal Grant and Cooperative Agreement Act; the Uniform Guidance (§ 200.204 Notices of funding opportunities and Appendix I to Part 200—Full Text of Notice of Funding Opportunity); and as further articulated by NIH specific guidance. The University, in good faith, commenced work, with an approved budget in place, relying on the funding to be reimbursed by NIH in accordance with award terms and conditions.

58. Using alternative university funds to continue work solicited by an external entity is neither possible given the nature of public fund accounting (aligning allowed uses of funds to their funding sources) nor practical due to the extremely limited availability of cash flow given recent state and federal reductions in support.

Conclusion

59. 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 13th 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



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.

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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] r , 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] d 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] 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 d § 50.406(a)
[12] 12 d § 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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

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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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:12 AM

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

8. Project Director or Principal Investigator
Manhattan E Charurat, PHD (Contact)
Professor
Redacted
Redacted

j . 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

18. Award Action Type
Supplement (REVISED)

1j . 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	
28. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,563,052

2j . 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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

Notice of Award

International Research Training Award
Department of Health and Human Services
National Institutes of Health

FOGARTY INTERNATIONAL CENTER

SECTION I – AWARD DATA – 3D43TW012284-03S2 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

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

SUMMARx TOTAL FEDERAL AWARD AMOUNT xEAR (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	**Y1,381,990**

SUMMARx TOTALS FOR ALL xEARS (for this Document Number)		
xR	**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 xear: 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 – PAxMENT$HOTLINE INFORMATION – 3D43TW012284-03S2 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 – 3D43TW012284-03S2 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

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 – 3D43TW012284-03S2 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

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.

AC/ NOWLEDGEMENT 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/.

HUMAN SUBKECT AND ANIMAL RESEARCH INFORMATION FOR TRAINING GRANTS – DELAxED 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 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 subZects and IRB approval information in Section G.1 JSpecial NOA terms and FOA reporting requirements" of the RPPR for each traineeSscholar 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:SSwww.fic.nih.govSGrantsSPagesSprogress-reports.asp" .
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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

UNIFORM GRANT GUIDANCE AND REVISED NIH GRANTS POLICx 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 POLICx STATEMENT ARE HEREBx INCORPORATED INTO THE TERMS OF THIS SUPPLEMENT.

SPREADSHEET SUMMARx
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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/23/2025 12:00 AM

EXHIBIT 6

Department of Health and Human Services
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Notice of Award
OAu D W43Y7 0122U4
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
SI uVLT, uYE RO MATECAI WB6ACYuMRTL
220 AT#h , Y RO# CLVLC2
6ACYuMRTLBMW21201

2. Congressional District of Recipient
0U

3. Payment System Identifier (ID)
1528002038A1

4. Employer Identification Number (EIN)
528002038

5. Data Universal Numbering System (DUNS)
1NN435911

6. Recipient's Unique Entity Identifier
Z9#TZKW42ZY1

7. Project Director or Principal Investigator
ManFattan L #FarHratBPh W(#ontact)
Professor
Redacted
Redacted

8. Authorized Official
KLI I LYh L OAh I L, YR#K
Redacted
Redacted

Federal Agency Information

9. Awarding Agency Contact Information
, AYA6WuTAE#h R7 Wh STE
Grants Management , pecialist
ORGATYE u YLTI AYuRI AC#LI YLT
satabdi.raycFowdFHry@niF.gov
301-498-9U50

10. Program Official Contact Information
Olora I Katz
Program
ORGATYE u YLTI AYuRI AC#LI YLT
flora.katz@niF.gov
301-402-9591

Federal Award Information

11. Award Number
3W43Y7 0122U4-03, 3

12. Unique Federal Award Identification Number (FAIN)
W43Y7 0122U4

13. Statutory Authority
42 S, # 2NUb 42 #OT 83a

14. Federal Award Project Title
, HpplementJuI , uGh YJRrientation

15. Assistance Listing Number
93.9N9

16. Assistance Listing Program Title
unternational TesearcF and TesearcF Yraining

17. Award Action Type
, Hpplement (TLVu, LW)

18. Is the Award R&D?
Ees

Summary Federal Award Financial Information	
19. Budget Period Start Date 0N/30/2024 – **End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Wrect #ost AmoHnt	$0
20 b. undirect #ost AmoHnt	$0
21. AHtForized #arryover	
22. Rffset	
23. Yotal AmoHnt of Oederal OHnds Rbligated tFis bHdget period	$U5B000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$U5B000
26. Project Period Start Date 0N/30/2024 – **End Date** 03/21/2025	
27. Yotal AmoHnt of tFe Oederal Award incIHding Approved #ost , Faring or MatcFing tFis Project Period	$3B583B052

28. Authorized Treatment of Program Income
Additional #osts

29. Grants Management Officer - Signature
6TS#L T 6SYTSM

30. Remarks

Acceptance of tFis awardBincIHding tFe "Yerms and #onditionsB is acknowledged by tFe recipient wFen fHnds are drawn down or otFerwise reqHested from tFe grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

l otice of Award

International Research Training Award
Wepartment of h ealtF and h Hman , ervices
l ational unstitHtes of h ealtF

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SECTION I – AWARD DATA – 3D43TW012274-03S3 REVISED

Principal Investigator(s):
ManFattan L #FarHrat (contact)BPh W
Al l A M MAl WACAKA, BMW
VisFwajit Caxmikant l imgaonkarBMW
" anet M YHranBPh W

Award e-mailed to: Redacted

Wear AHtForized Rfficial:

YFe l ational unstitHtes of h ealtF Fereby revises tFis award (see "Award #alcHlation' in , ection uand "Yerms and #onditions' in , ection uu) to Sl uVLT, uYE ROMATECAl W6ACYuMRTL in sHpport of tFe above referenced project. YFis award is pHrsHant to tFe aHtFority of 42 S, # 2NUb 42 #OT 83a and is sHbject to tFe reqHirements of tFis statHte and regHlation and of otFer referencedBincorporated or attacFed terms and conditions.

Acceptance of tFis awardBincIHding tFe "Yerms and #onditionsB is acknowledged by tFe recipient wFen fHnds are drawn down or otFerwise reqHested from tFe grant payment system.

LacF pHblicationBpress releaseBor otFer docHment aboHt researcF sHpported by an l uh award mHst incIHde an acknowledgment of l uh award sHpport and a disclaimer sHcF as "TesearcF reported in tFis pHblication was sHpported by tFe Oogarty unternational #enter of tFe l ational unstitHtes of h ealtF Hnder Award l Hmber W43Y7 0122U4. YFe content is solely tFe responsibility of tFe aHtFors and does not necessarily represent tFe official views of tFe l ational unstitHtes of h ealtF.' Prior to issHing a press release concerning tFe oHtcome of tFis researcFBplease notify tFe l uh awarding u# in advance to allow for coordination.

Award recipients mHst promote objectivity in researcF by establisFing standards tFat provide a reasonable expectation tFat tFe designBcondHct and reporting of researcF fHnded Hnder l uh awards will be free from bias resHlting from an unvestigator§ Oinancial #onflict of unterest (O#Ru)Bin accordance witF tFe 2011 revised regHlation at 42 #OT Part 50 , Hbpart O. YFe unstitHtion sFall sHbmit all O#Rureports to tFe l uh tFroHgF tFe eTA #ommons O#RuModHle. YFe regHlation does not apply to PFase u, mall 6Hsiness unnovative TesearcF (, 6uT) and , mall 6Hsiness YecFnology Yransfer (, YYT) awards. #onsHlt tFe l uh website Fttp://grants.niF.gov/grants/policy/coi/ for a link to tFe regHlation and additional important information.

uf yoH Fave any qHestions aboHt tFis awardBplease direct qHestions to tFe Oederal Agency contacts.

, incerely yoHrsB

6TS#L T 6SYTSM
Grants Management Rfficer
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Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)
Other $89B444

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

Federal Direct Costs	$89[illegible]44
Federal F&A Costs	$5[illegible]558
Approved Budget	$U5[illegible]000
Total Amount of Federal Funds Authorized (Federal Share)	$U5[illegible]000
TOTAL FEDERAL AWARD AMOUNT	$U5[illegible]000

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for tFis WocHment l Hmber)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3W43Y7 0122U4-03, 3	$U5[illegible]000
5W43Y7 0122U4-03	$1[illegible]38[illegible]244
3W43Y7 0122U4-03, 1	$180[illegible]U48
3W43Y7 0122U4-03, 2	$100[illegible]000
TOTAL	**$1,371,990**

SUMMARY TOTALS FOR ALL YEARS (for tFis WocHment l Hmber)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$U5[illegible]000	$1[illegible]U1[illegible]990

Fiscal Information:
Payment System Identifier: 1528002038A1
Document Number: WY7 0122U4A
PMS Account Type: P (, HbaccoHnt)
Fiscal Year: 2024

u#	#Al	2024
Y7	N4U838U	$U5[illegible]000

NIH Administrative Data:
PCC: GC6COLCR / **OC**: 41012 / **Released**: 03/21/2025
Award Processed: 03/24/2025 12:0N:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3D43TW012274-03S3 REVISED

Oor payment and h h, Rffice of unspector General h otline informationBsee tFe l uh h ome Page at Fttp://grants.niF.gov/grants/policy/awardconditions.Ftm

SECTION III – STANDARD TERMS AND CONDITIONS – 3D43TW012274-03S3 REVISED

YFis award is based on tFe application sHbmitted toBand as approved byBl uh on tFe above-titled project and is sHbject to tFe terms and conditions incorporated eitFer directly or by reference in tFe following:

a. YFe grant program legislation and program regHlation cited in tFis l otice of Award.
b. #onditions on activities and expenditHre of fHnds in otFer statHtory reqHirementsBsHcF as tFose inclHded in appropriations acts.
c. 45 #OT Part U5.
d. l ational Policy TeqHirements and all otFer reqHirements described in tFe l uh Grants Policy , tatementBinclHding addenda in effect as of tFe beginning date of tFe bHdget period.
e. Oederal Award Performance Goals: As reqHired by tFe periodic report in tFe TPPT or in tFe final progress report wFen applicable.
f. YFis award noticeBU #CSWU G Yh L YLTM, Al W#Rl WUYuRl , #uYLW6LCR7 .

(, ee l uh h ome Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

Research and Development (R&D): All awards issHed by tFe l ational unstitHtes of h ealtF (l uh) meet tFe definition of "TesearcF and Wevelopment' at 45 #OT Part& U5.2. As sHcFBaHditees sFoHld identify l uh awards as part of tFe T; WclHster on tFe , cFedHle of LxpenditHres of Oederal Awards (, LOA). YFe aHditor

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

sFoHld test l uh awards for compliance as instrHcted in Part VB#IHsters of Programs. l uh recognizes tFat some awards may Fave anotFer classification for pHrposes of indirect costs. YFe aHditor is not reqHired to report tFe disconnect (i.e.BtFe award is classified as T; Wfor Oederal AHdit TeqHirement pHrposes bHt non-researcF for indirect cost rate pHrposes)BHnless tFe aHditee is cFarging indirect costs at a rate otFer tFan tFe rate(s) specified in tFe award docHment(s).

An Hnobligated balance may be carried over into tFe next bHdget period witFoHt Grants Management Rfficer prior approval.

YFis grant is excIHded from , treamlined l oncompeting Award ProcedHres (, l AP).

YFis award is sHbject to tFe reqHirements of 2 #OT Part 25 for institHtions to obtain a HniqHe entity identifier (SLu) and maintain an active registration in tFe , ystem for Award Management (, AM). , FoHld a consortiHm/sHbaward be issHed Hnder tFis awardBa SLureqHirement mHst be incIHded. , ee Fttp://grants.niF.gov/grants/policy/awardconditions.Ftm for tFe fHIl l uh award term implementing tFis reqHirement and otFer additional information.

YFis award Fas been assigned tFe Oederal Award udentification l Hmber (OAul) W43Y7 0122U4. Tecipients mHst docHment tFe assigned OAul on eacF consortiHm/sHbaward issHed Hnder tFis award.

6ased on tFe project period start date of tFis projectBtFis award is likely sHbject to tFe Yransparency Act sHbaward and execHtive compensation reporting reqHirement of 2 #OT Part 1U0. YFere are conditions tFat may excIHde tFis award–see Fttp://grants.niF.gov/grants/policy/awardconditions.Ftm for additional award applicability information.

un accordance witF P.C. 110-181Bcompliance witF tFe l uh PHblic Access Policy is now mandatory. Oor more informationBsee l RY-RW-0N-033 and tFe PHblic Access website: Fttp://pHblicaccess.niF.gov/.

YFis award represents tFe final year of tFe competitive segment for tFis grant. , ee tFe l uh Grants Policy , tatement , ection N.8 #loseoHt for complete closeoHt reqHirements at: Fttp://grants.niF.gov/grants/policy/policy.FtmDgps.

A final expenditHre Oederal Oinancial Teport (OOT) (, O 425) mHst be sHbmitted tFroHgF tFe Payment Management , ystem (PM,) witFin 120 days of tFe period of performance end date–see tFe l uh Grants Policy , tatement , ection N.8.1 Oinancial TeportsBFttp://grants.niF.gov/grants/policy/policy.FtmDgpsBfor additional information on tFis sHbmission reqHirement. YFe final OOT mHst indicate tFe exact balance of Hnobligated fHnds and may not reflect any HnliqHidated obligations. YFere mHst be no discrepancies between tFe final OOT expenditHre data and tFe real-time casF drawdown data in PM, . l uh will close tFe awards Hsing tFe last recorded casF drawdown level in PM, for awards tFat do not reqHire a final OOT on expenditHres. ut is important to note tFat for financial closeoHtBif a grantee fails to sHbmit a reqHired final expenditHre OOTBl uh will close tFe grant Hsing tFe last recorded casF drawdown level.

A Oinal unvention , tatement and #ertification form (h h , 58N)B(not applicable to trainingBconstrHctionB conference or cancer edHcation grants) mHst be sHbmitted witFin 120 days of tFe expiration date. YFe h h , 58N form may be downloaded at: Fttp://grants.niF.gov/grants/forms.Ftm. YFis paragrapF does not apply to Yraining grantsBOellowsFipsBand certain otFer programsX i.e.Bactivity codes #08BW42BW43BWU1BWPUBG0UB G0NBG11BK12BK18BK30BP09BP40BP41BP51BT13BT25BT2NBT30BT90BTC5BTC9B, 10B, 14B, 15BS13BS14BS41B S42BS45BS#8BS#UBST2B_01B_02.

Snless an application for competitive renewal is sHbmittedBa Oinal TesearcF Performance Progress Teport (Oinal TPPT) mHst also be sHbmitted witFin 120 days of tFe period of performance end date. uf a competitive renewal application is sHbmitted prior to tFat dateBtFen an unterim TPPT mHst be sHbmitted by tFat date as well. unstrHctions for preparing an unterim or Oinal TPPT are at: Fttps://grants.niF.gov/grants/rppr/rpprJinstrHctionJgHide.pdf. Any otFer specific reqHirements set fortF in tFe terms and conditions of tFe award mHst also be addressed in tFe unterim or Oinal TPPT. *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*.

l uh reqHires electronic sHbmission of tFe final invention statement tFroHgF tFe #loseoHt featHre in tFe #ommons.

l RYL: uf tFis is tFe final year of a competitive segment dHe to tFe transfer of tFe grant to anotFer institHtionB tFen a Oinal TPPT is not reqHired. howeverBa final expenditHre OOT is reqHired and mHst be sHbmitted

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

electronically as noted above. uf not already sHbmittedBtFe Oinal unvention , tatement is reqHired and sFoHld be sent directly to tFe assigned Grants Management , pecialist.

Tecipients mHst administer tFe project in compliance witF federal civil rigFts laws tFat proFibit discrimination on tFe basis of raceBcolorBnational originBdisabilityBageBand comply witF applicable conscience protections. YFe recipient will comply witF applicable laws tFat proFibit discrimination on tFe basis of sexBwFicF incIHdes discrimination on tFe basis of gender identityBsexHal orientationBand pregnancy. #ompliance witF tFese laws reqHires taking reasonable steps to provide meaningfHl access to persons witF limited LnglisF proficiency and providing programs tFat are accessible to and Hsable by persons witF disabilities. YFe h h , Rffice for #ivil TigFts provides gHidance on complying witF civil rigFts laws enforced by h h , . , ee Fttps://www.FFs.gov/civil-rigFts/for-providers/provider-obligations/index.Ftml and Fttps://www.FFs.gov/.

- Tecipients of OOA mHst ensHre tFat tFeir programs are accessible to persons witF limited LnglisF proficiency. Oor gHidance on meeting tFe legal obligation to take reasonable steps to ensHre meaningfHl access to programs or activities by limited LnglisF proficient individHalsB see Fttps://www.FFs.gov/civil-rigFts/for-individHals/special-topics/limited-englisF-proficiency/fact-sFeet-gHidance/index.Ftml and Fttps://www.lep.gov.
- Oor information on an institHtionSs specific legal obligations for serving qHalified individHals witF disabilitiesBincIHding providing program accessBreasonable modificationsBand to provide effective commHnicationBsee Fttp://www.FFs.gov/ocr/civilrigFts/Hnderstanding/disability/index.Ftml.
- h h , fHnded FealtF and edHcation programs mHst be administered in an environment free of sexHal Farassment–see Fttps://www.FFs.gov/civil-rigFts/for-individHals/sex-discrimination/index.Ftml. Oor information aboHt l uh 's commitment to sHpporting a safe and respectfHl work environmentB wFo to contact witF qHestions or concernsBand wFat l uh 's expectations are for institHtions and tFe individHals sHpported on l uh -fHnded awardsBplease see Fttps://grants.niF.gov/grants/policy/Farassment.Ftm.
- Oor gHidance on administering programs in compliance witF applicable federal religioHs nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination lawsBsee Fttps://www.FFs.gov/conscience/conscience-protections/index.Ftml and Fttps://www.FFs.gov/conscience/religioHs-freedom/index.Ftml.

un accordance witF tFe regHlatory reqHirements provided at 45 #OT U5.113 and Appendix _ uuto 45 #OT Part U5Brecipients tFat Fave cHrrently active Oederal grantsBcooperative agreementsBand procHrement contracts witF cHmHlative total valHe greater tFan $10B000B000 mHst report and maintain information in tFe , ystem for Award Management (, AM) aboHt civilBcriminalBand administrative proceedings in connection witF tFe award or performance of a Oederal award tFat reacFed final disposition witFin tFe most recent five-year period. YFe recipient mHst also make semiannHal disclosHres regarding sHcF proceedings. Proceedings information will be made pHblicly available in tFe designated integrity and performance system (cHrrently tFe Oederal Awardee Performance and ntegrity nformation , ystem (OAPu;)). OHll reporting reqHirements and procedHres are foHnd in Appendix _ uuto 45 #OT Part U5. YFis term does not apply to l uh fellowsFips.

Treatment of Program Income:
Additional #osts

SECTION IV – TW SPECIFIC AWARD CONDITIONS – 3D43TW012274-03S3 REVISED

#linical Yrial ndicator: l o
YFis award does not sHpport any l uh -defined #linical Yrials. , ee tFe l uh Grants Policy , tatement , ection 1.2 for l uh definition of #linical Yrial.

Grant Yermination
ut is tFe policy of l uh not to prioritize TesearcF programs based primarily on artificial and non-scientific categoriesBincIHding amorpFoHs eqHity objectivesBare antitFetical to tFe scientific inqHiryBdo notFing to expand oHr knowledge of living systemsBprovide low retHrns on investmentBand HltimatelydoFnot enFance FealtFBlengtFen lifeBor redHce illness. 7 orseBso-called diversityBeqHityBand incIHsion (”WLú) stHdies are often Hsed to sHpport HnlawfHl discrimination on tFe basis of race and otFer protected cFaracteristicsB wFicF Farms tFe FealtF of Americans. YFereforeBit is tFe policy of l uh not to prioritize sHcF researcF programs. YFereforeBtFis project is terminated. SI uVLT, uYE RO MATECAl W6ACYuMRTL may reqHest fHnds to sHpport patient safety and orderly closeoHt of tFe project. OHnds Hsed to sHpport any otFer researcF activities will be disallowed and recovered. Please be advised tFat yoHr organizationBas part of tFe orderly closeoHt process will need to sHbmit tFe necessary closeoHt docHments (i.e.BOinal TesearcF Performance

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

Progress TeportBOinal unvention , tatementBand tFe Oinal Oederal Oinancial Teport (OOT)B**as applicable**) witFin 120 days of tFe end of tFis grant.

l uh is taking tFis enforcement action in accordance witF 2 #.O.T. & 200.340 as implemented in l uh GP, , ection N.5.2. YFis revised award represents tFe final decision of tFe l uh . ut sFall be tFe final decision of tFe Wepartment of h ealtF and h Hman , ervices (h h ,) Hnless witFin 30 days after receiving tFis decision yoH mail or email a written notice of appeal to Wr. MattFew Memoli. Please incIHde a copy of tFis decisionByoHr appeal jHstificationBtotal amoHnt in dispHteBand any material or docHmentation tFat will sHpport yoHr position. OinallyBtFe appeal mHst be signed by tFe institHtional official aHtForized to sign award applications and mHst be dated no later tFan 30 days after tFe date of tFis notice.

YFis revision is made per tFe letter dated MarcF 21B2025 and sHpersedes tFe l otice of AwardB(l oA) issHed: 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

YFe progress report for tFe parent award mHst incIHde separate progress Hpdate(s) for tFis sHpplement.

ACKNOWLEDGEMENT OF FUNDING

LacF pHblicationBpress releaseBor otFer docHment aboHt researcF sHpported by an l uh award mHst incIHde acknowledgment of Ou# and l uh award sHpport witF tFe following or comparable footnote and disclaimer:
TesearcF reported in tFis pHblication was sHpported by tFe Oogarty unternational #enter of tFe l ational unstitHtes of h ealtF. YFe content is solely tFe responsibility of tFe aHtFors and does not necessarily represent tFe official views of tFe l ational unstitHtes of h ealtF.
Prior to issHing a press release concerning tFe oHtcome of tFis researcFBplease notify tFe l uh awarding u# in advance to allow for coordination.
YFis pHblication reqHirement applies not only to tFe primary granteeBbHt also to any sHbcontractors and /or trainees involved witF tFe project.
Oor additional informationBplease visit Fttp://www.niF.gov/aboHt/pHblicaccess/.

UNIFORM GRANT GUIDANCE AND REVISED NIH GRANTS POLICY STATEMENT

Per l otice l Hmber l RY-RW-15-048BtFe Wepartment of h ealtF and h Hman , ervices pHblisFed an interim rHle adapting RM6§ final Sniform Grant GHidance in 2 #OT part 200 witF certain amendmentsBbased on existing h h , regHlationsBto sHpplement tFe gHidance as needed for tFe Wepartment effective Wecember 28B 2014. YFe cHrrent revised l uh Grants Policy , tatement is applicable to all l uh grants and cooperative agreements.
unformation regarding tFe l uh Grants Policy , tatement can be foHnd at: Fttps://grants.niF.gov/policy/index.Ftm
h igFligFted below are some select items of costs of particHlar note to Ou# grant recipients:

- O; A for Ooreign and unternational Rrganizations: l uh and Ou# continHe to provide O; A costs Hnder grants to foreign and international organizations will be fHnded at a rate of N percent of modified total direct costsBexcIHsive of eqHipmentBtHition and related feesBand sHbawards in excess of $25B000. YFese fHnds are paid to sHpport tFe costs of compliance witF federal reqHirements. YFis applies to direct foreign awards and foreign sHbawards.
- O; A for #areer/OellowsFip/Yraining Awards: l uh and Ou# continHe to provide O; A costs Hnder researcF trainingBsome edHcation grantsBand #areer (K) awards will be fHnded at a rate of N percent of modified total direct costsBexcIHsive of tHition and feesBFealtF insHrance (wFen awarded as part of tHition and fees)BeqHipmentBand consortiHms in excess of $25B000Bconsistent witF existing policy.
- ValHe Added Yax: Ooreign taxes cFarged for tFe pHrcFase of goods or services tFat a non-Oederal entity is legally reqHired to pay in coHntry is an allowable expense Hnder Oederal awards. howeverB for many coHntries an exemption of tFis tax for researcF exists. #onseqHentlyBreqHesting tFis cost sFoHld be Hnallowable for researcF grants involving sHcF coHntries as a performance site.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

- Visa #osts: Visa costs may be allowable wFen identified in specific ORAs or wFen witFin tFe scope of an approved researcF project. GenerallyBallowable direct cost as part of recrHiting costs on an I uh grantBas long as tFe institHtion Fas an employee/employer relationsFip witF tFe individHal.

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: 3W43Y7 0122U4-03, 3 TLVu, LW

INSTITUTION: SI uVLT, uYE RO MATECAl W6ACYuMRTL

6Hdget	Eear 3
RtFer	$89B444
YRYAC OLWLTAC W#	$89B444
YRYAC OLWLTAC O; A	$5B558
YRYAC #R, Y	$U5B000

Oacilities and Administrative #osts	Eear 3
O; A #ost Tate 1	N%
O; A #ost 6ase 1	$89B444
O; A #osts 1	$5B558

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/24/2025 12:0N AM

EXHIBIT 7

National Institutes of Health
Office of Extramural Research

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.

[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
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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

04/07/2025

University of Maryland Baltimore
Sponsored Programs Administration
620 W. Lexington St, 4th Floor
Baltimore, MD 21201

Christine R. Toalepai:

Funding for Project Number 1UC2CA293782-01 is hereby terminated pursuant to the 2024 National Institutes of Health (NIH) Grants Policy Statement, and 2 C.F.R. § 200.340(a)(4). This letter serves as a termination notice.

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/29/2024, and obligations for federal grants are generally determined by the laws, regulations, and terms in effect at the time the grant was awarded, as outlined in the Notice of Award (NOA) or grant agreement . This includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.

According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340. At the time your grant was issued, 2 C.F.R. § 200.340(a)(4) 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 project no longer effectuates agency priorities. 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, there is no modification of the project that would align with agency priorities.

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.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §200.344. However, due to the immediate termination of this project, NIH may require a shortened timeframe to submit closeout reports. Details will be provided in the revised NOA issued by the Grants Management Official.

Administrative Appeal

Should you object to the termination, you may provide information and documentation challenging this action. You must submit a request for such review to Acting Principal Deputy Director Dr. Memoli (matthew.memoli nih.gov) no later than 30 days after the date of this letter. You may submit an extension request to Dr. Memoli and provide good cause as to why an extension of time should be granted.

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.

Sincerely,

Crystal Wolfrey

Crystal Wolfrey
Chief Grants Management Officer
National Cancer Institute

cc:
OPERA Director
Deputy Director for Extramural Research

EXHIBIT 12

Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 at 3:33:40 PM Eastern Daylight Time
From: Bulls, Michelle G. (NIH/OD) [E]
To: Paffrath, Dennis
Attachments: image001.jpg, image002.png

CAUTION: This message originated from a non-UMB email system. Hover over any links before clicking and use caution opening attachments.





4/8/2025

Dennis Paffrath
University Of Maryland Baltimore
Redacted

Dear Dennis Paffrath:

Effective with the date of this letter, funding for Project Number 5U54CA272205-03 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 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 Crystal Wolfrey, Chief Grants Management Officer, NCI
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

Subject: Fwd: NIGMS Funding Update
Date: Wednesday, April 2, 2025 at 1:38:14 PM Eastern Daylight Time
From: Sorensen, Gregory J.
To: Frankenfield, Jill

Here is another one. Not sure if you received it yet. Thanks

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

Begin forwarded message:

From: "Gibbs, Kenneth (NIH/NIGMS) [E]" <kenneth.gibbs@nih.gov>
Subject: NIGMS Funding Update
Date: April 2, 2025 at 1:15:12 PM EDT
To: Redacted

You don't often get email from kenneth.gibbs@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.

Re: GM113262-10

Dear Sorenson, Gregory,

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 14

Subject: Fwd: NIGMS Funding Update
Date: Wednesday, April 2, 2025 at 1:39:06 PM Eastern Daylight Time
From: Sorensen, Gregory J.
To: Frankenfield, Jill

And another one. Thanks

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

Begin forwarded message:

From: "Gibbs, Kenneth (NIH/NIGMS) [E]" <kenneth.gibbs@nih.gov>
Subject: NIGMS Funding Update
Date: April 2, 2025 at 1:15:34 PM EDT
To: Redacted

You don't often get email from kenneth.gibbs@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.

Re: GM144951-04

Dear Christine R. Toalepai,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** 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 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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

(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-

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

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:

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 9/20/2024 12:16 AM

EXHIBIT C

National Institutes of Health
Office of Extramural Research

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.

Version:13 - 8/3/2022 12:59 PM | Generated on: 2/1/2023 12:18 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 2/1/2023 12:18 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 2/1/2023 12:18 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 2/1/2023 12:18 AM

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

Version: 13 - 8/3/2022 12:59 PM | Generated on: 2/1/2023 12:18 AM

EXHIBIT E

National Institutes of Health
Office of Extramural Research

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	b16Q8026
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@

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Sin) erelwwours3

Pris) illa Grant
Grants Managev ent Offi) er
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@
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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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/16/2024 12:25 AM

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	b693MJ	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	b19W80W6
8&A Costs 1	b16Q3026	b1243210	b1153629	b1123910

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/16/2024 12:25 AM

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/16/2024 12:25 AM

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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:03 AM

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

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 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.

Version:25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

- 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,

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 7/19/2024 12:19 AM

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 on Drug Abuse (NIDA)
Funding Opportunity Title	NIH Helping to End Addiction Long-term® Initiative (NIH HEAL Initiative®) Research Program to Optimize Medications for Opioid Use Disorder (OUD) (UG3/UH3 Clinical Trial Required)
Activity Code	UG3/UH3
Announcement Type	New
Related Notices	• October 26, 2022 - Re-issuance: PAR-23-039 to Clarify Application Instructions and Review Criteria. See Publication of Publication of 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 results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact / Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Reviewers will consider each of the review criteria 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 a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA: Does the application make a compelling case that the presence of a Center at this institution will have a high likelihood to enhance the scientific knowledge of the faculty relevant for the conduct of research on minority health and health disparities and appropriately engage the community?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial justified? Are the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature? Is the proposed clinical trial the best way to establish or refute the hypothesis? Is the clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community norms or health or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is the trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well-suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: Are the academic qualifications, research experience, and productivity of members, including those from other institutions appropriate to contribute to the research training and education at other faculty members?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and to recruit participants and monitor? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and are the roles and responsibility of each of participating investigators and staff(s) for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the type of prior research that serves as the key support for the proposed project? Have the investigators provided strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will the investigators have adequate means to manage? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

1) the protection of human subjects from research risks; and
2) 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), justified in terms of the scientific goals and research setting proposed?

Specific to this NOFO: To what extent are the strategies for overseeing, managing and coordinating the entire range of proposed activities, establishing the appropriate measures for monitoring and assessing progress, and for ensuring that component plans are implemented likely to be successful?

To what extent is the Management Plan described in sufficient detail to outline the organizational and governance structure in a manner that the roles and responsibilities are clear and likely to succeed at managing and coordinating of the proposed Center activities?

To what extent does the proposed Evaluation Plan include the appropriate strategies and measures to determine the ongoing Center performance and project management to ensure successful completion of the stated aims and the achievement of the desired results and purpose of the NIMHD Centers of Excellence initiative?

To what extent will the programmatic activities (e.g., seminars, workshops, or other activities) that will be undertaken support career enhancement for faculty from a variety of disciplines at the institution?

To what extent are the 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?

To what extent is the plan for subsidies/faculty mentorship to the pilot project recipients well described? Is the goal of becoming an independent researcher through applications for research grants (e.g., NIH R01 or equivalent) clearly articulated? Is the mentorship plan (such as a mentored R-award or equivalent and ultimately a R01 grant) well described and likely to be successful?

To what extent are the institutional review procedures in place to ensure 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 adequate?

To what extent will the activities conducted for the timely and appropriate dissemination of information generated by the Center, its pilot projects, and other activities for diverse audiences, including the non-scientific public (lay) facilitate equitable and collaborative relationships with the community and other stakeholders?

If there are foreign component(s), to what extent has the applicant adequately justified how the proposed activities at foreign sites will contribute to the knowledge that will improve minority health and/or help to reduce or eliminate health disparities in the United States?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable:

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study adequately designed to test for safety and/or effectiveness? Is the control condition adequate? Are potential confounding variables addressed? Is the sample size adequate to power the study and to control for variance in participant characteristics? Are the study populations (sex, gender, age, demographic group), proposed intervention arms/doses, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (to rule), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to participation and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s) from the supplying entity, if not commercially available (resources, as applicable)?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or center/laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Specific to this FOA: To what extent do the institutional letters of support indicate that the applicant institution is fully committed to achieving the specific aims of the proposed Center?

In addition, for applications involving clinical trials

Is personnel, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-site/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

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 projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize 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 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 research involving the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Guidelines 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, biosecurity, 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 governance and management structure appropriate to ensure that component plans are implemented?
- Are the roles and responsibilities of each participating investigator 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 a robust Evaluation Plan provided that 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 advisory 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' activities, 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 NIMHD, 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 PD/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 awarded is expected to be the basis for NIH support, 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 2 specific terms and conditions identified in this 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), the "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 must review the procedures for obtaining informed consent and the plans for protecting the privacy of participants.

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.
- 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:

- Federal-wide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgement of Federal Funding

For recipient to successfully and receive 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 Department 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 that recipients provide meaningful access for persons with limited English proficiency and to persons with limited English proficiency and ensuring effective communication 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/section-1557/publication-of-the-1557-publication/index.html#publication.

HHS recognizes that research projects are described in detail in the application and may change many times during the course of the project. Disclosures, assurances, certifications, and other representations made in the application are treated as binding obligations of the awardee. Changes in the project and budget after the award is made often require prior approval of the awarding agency. See the NIH Policy on Publication and Publication Info for more information.

HHS recognizes that research projects are described in detail in the application and may change many times during the course of the project. Disclosures, assurances, certifications, and other representations made in the application are treated as binding obligations of the awardee. Changes in the project and budget after the award is made often require prior approval of the awarding agency. See the NIH

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

OMB Number: 4040-0001
Expiration Date: 11/30/2025

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
Table Of Contents

SF 424 R&R Cover Page ... 1
Table of Contents ... 3
Summaries ... 5
Component Summary ... 5
Performance Sites Summary ... 6
Human Subjects - Clinical Trials - Vertebrate Animals - HESC - Human Fetal Tissue Summary ... 8
Study Summary ... 9
Composite Application Budget Summary ... 10
Component Budget Summary ... 11
Categories Budget Summary ... 13
Senior/Key personnel Summary ... 21
Biosketches ... 22
Performance Sites ... 62
Research & Related Other Project Information ... 65
Project Summary/Abstract(Description) ... 66
Project Narrative ... 67
Facilities & Other Resources ... 68
Equipment ... 88
Other Attachments ... 89
UB_VPHS_effort_attestation ... 89
Special_Eligibility_Requirements ... 90
Research & Related Senior/Key Person ... 98
PHS398 Cover Page Supplement ... 104
PHS 398 Research Plan ... 106
Specific Aims ... 107
Research Strategy ... 108
PHS Human Subjects and Clinical Trials Information ... 114
Bibliography & References Cited ... 117
Letters of Support ... 119
Other Plan(s) ... 134
Admin-Core ... 135
Admin-Core-001 (344) - Igniting Hope in Buffalo New York communities: Training th e Next Generation of Health Equity Researchers ... 135
Performance Sites ... 136
Research & Related Other Project Information ... 139
Project Summary/Abstract(Description) ... 140
Research & Related Senior/Key Person ... 141
Research & Related Budget Year - 1 ... 143
Research & Related Budget Year - 2 ... 146
Research & Related Budget Year - 3 ... 149
Research & Related Budget Year - 4 ... 152
Research & Related Budget Year - 5 ... 155
Budget Justification ... 158
Research & Related Cumulative Budget ... 163
PHS398 Cover Page Supplement ... 165
PHS 398 Research Plan ... 167
Specific Aims ... 168
Research Strategy ... 169
PHS Human Subjects and Clinical Trials Information ... 175
Bibliography & References Cited ... 177
Core ... 178
Core-001 (154) - Igniting Hope in Buffalo New York communities: Training the Next

Generation of Health Equity Researchers ... 178
Performance Sites ... 179
Research & Related Other Project Information ... 182
Project Summary/Abstract(Description) ... 183
Research & Related Senior/Key Person ... 184
Research & Related Budget Year - 1 ... 187
Research & Related Budget Year - 2 ... 190
Research & Related Budget Year - 3 ... 193
Research & Related Budget Year - 4 ... 196
Research & Related Budget Year - 5 ... 199
Budget Justification ... 202
Research & Related Cumulative Budget ... 205
PHS398 Cover Page Supplement ... 207
PHS 398 Research Plan ... 209
Specific Aims ... 210
Research Strategy ... 211
PHS Human Subjects and Clinical Trials Information ... 217
Bibliography & References Cited ... 219
Investigator-Core ... 221
Investigator-Core-001 (358) - Igniting Hope in Buffalo New York communities: Trai
ning the Next Generation of Health Equity Researchers ... 221
Performance Sites ... 222
Research & Related Other Project Information ... 225
Project Summary/Abstract(Description) ... 226
Research & Related Senior/Key Person ... 227
Research & Related Budget Year - 1 ... 230
Research & Related Budget Year - 2 ... 233
Research & Related Budget Year - 3 ... 236
Research & Related Budget Year - 4 ... 239
Research & Related Budget Year - 5 ... 242
Budget Justification ... 245
Research & Related Cumulative Budget ... 248
PHS398 Cover Page Supplement ... 250
PHS 398 Research Plan ... 252
Specific Aims ... 253
Research Strategy ... 254
PHS Human Subjects and Clinical Trials Information ... 266
Bibliography & References Cited ... 270

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**

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 38 of 375

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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 39 of 375

	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**

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 40 of 375

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**

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 41 of 375

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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 42 of 375

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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 43 of 375

	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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 44 of 375

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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 45 of 375

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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 46 of 375

	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

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 47 of 375

	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**

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 48 of 375

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

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

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/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

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/

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

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.

- o 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**
  - o 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.
  - o 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.

- 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.
- 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.
- 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.
- 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**
  - 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).
  - 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.
  - 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.
  - 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.
  - 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

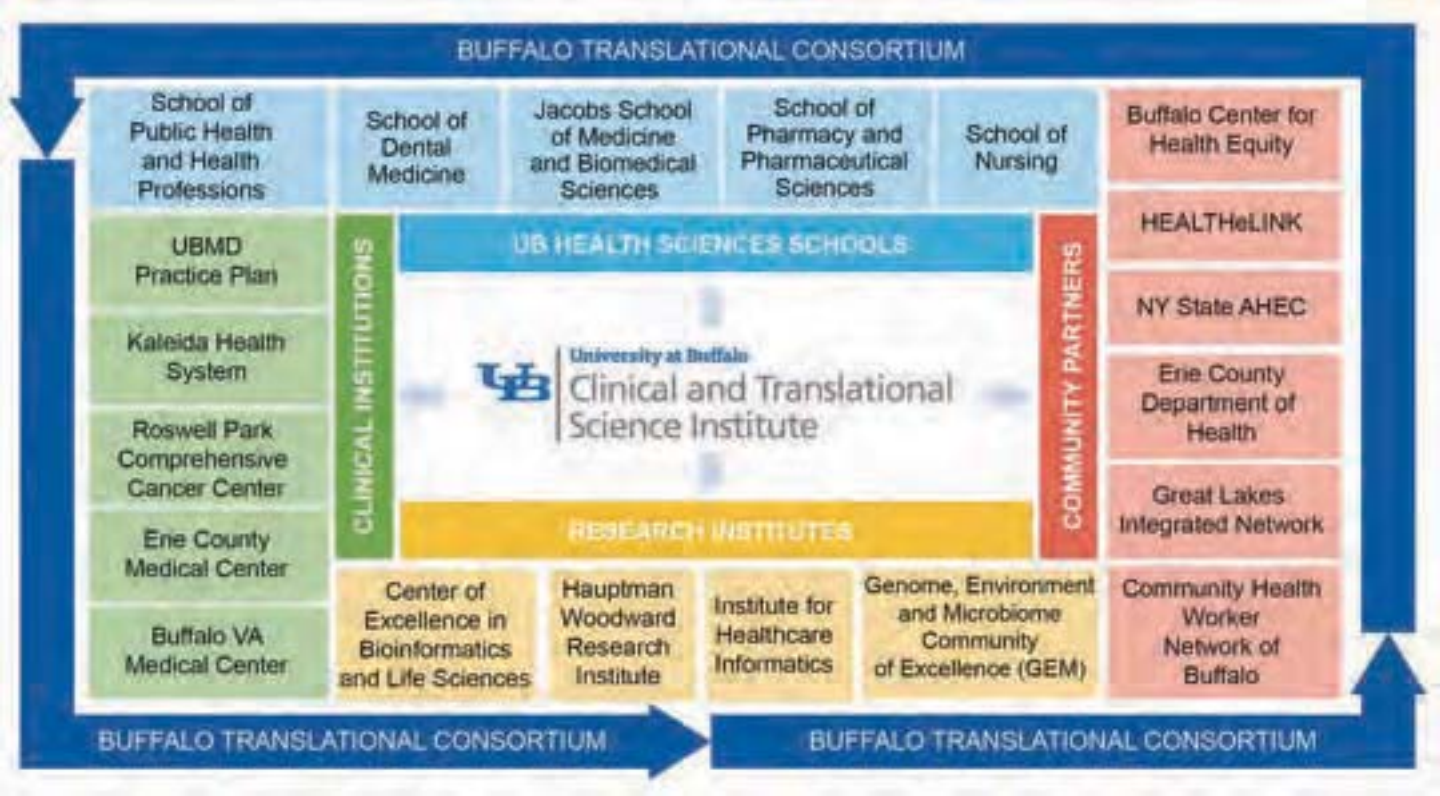
- The UB School of Management has been recognized by *The Wall Street Journal* as one of the best in the world for seven consecutive years. The mission of the school is to discover and deepen our understanding of management concepts and applications that drive effective organizations and use them to 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.

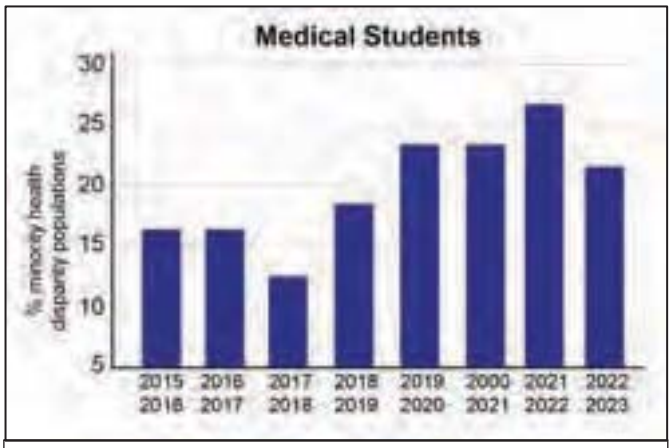


Figure 1. Percent of medical students admitted who are members of minority health disparity populations or other health disparity populations by year.

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.

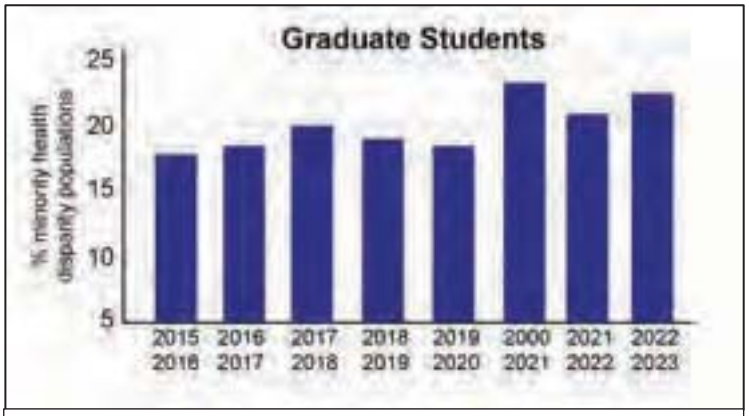


Figure 2. Percent of graduate students admitted who are members of minority health disparity populations or other health disparity populations by year.

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.

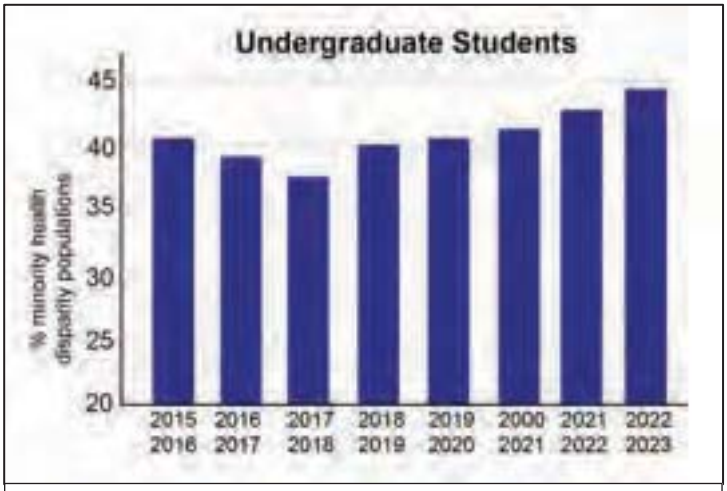


Figure 3. Percent of undergraduate students who are members of NIH-designated minority health disparity populations or other health disparity populations admitted to the School of Medicine by year

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.

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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

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Degree Type: Degree Year:

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Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Grinslade_Bio.pdf

Attach Current & Pending Support: File Name:

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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

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Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Orom_Bio_.pdf

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PROFILE - Senior/Key Person

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Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Pointer_Bio.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

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Degree Type: Degree Year:

Attach Biographical Sketch*: File Name: Silverman_Bio.pdf

Attach Current & Pending Support: File Name:

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Degree Type: Degree Year:

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PROFILE - Senior/Key Person

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Degree Type: Degree Year:

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Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

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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

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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.

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.

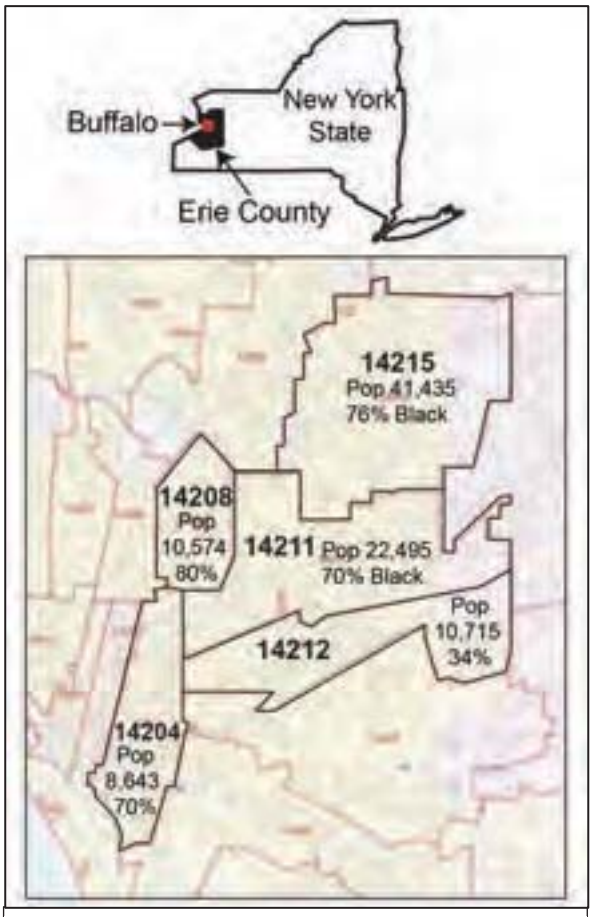


Figure A2. Map of five ZIP codes on Buffalo's East Side, showing population (Pop) and percent of Black residents. Source: U.S. Census and Social Variables Database of Buffalo East Side - H. Taylor, UB Center for Urban Studies.

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.

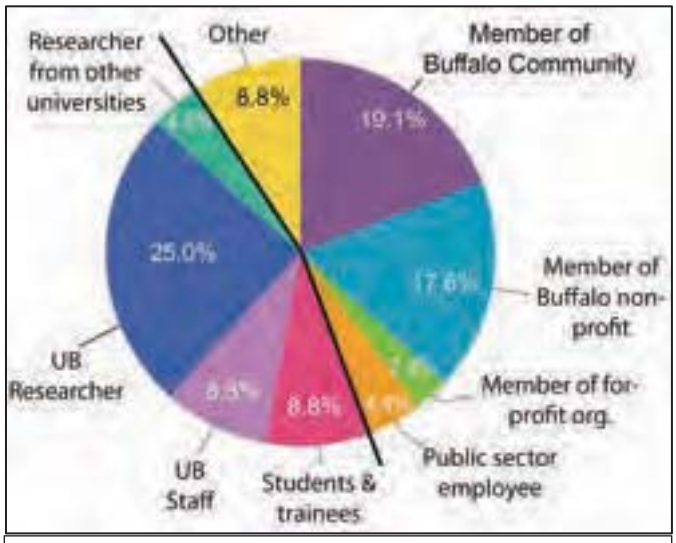


Figure A3. Breakdown of attendees of the 2021 Igniting Hope Conference

- 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.

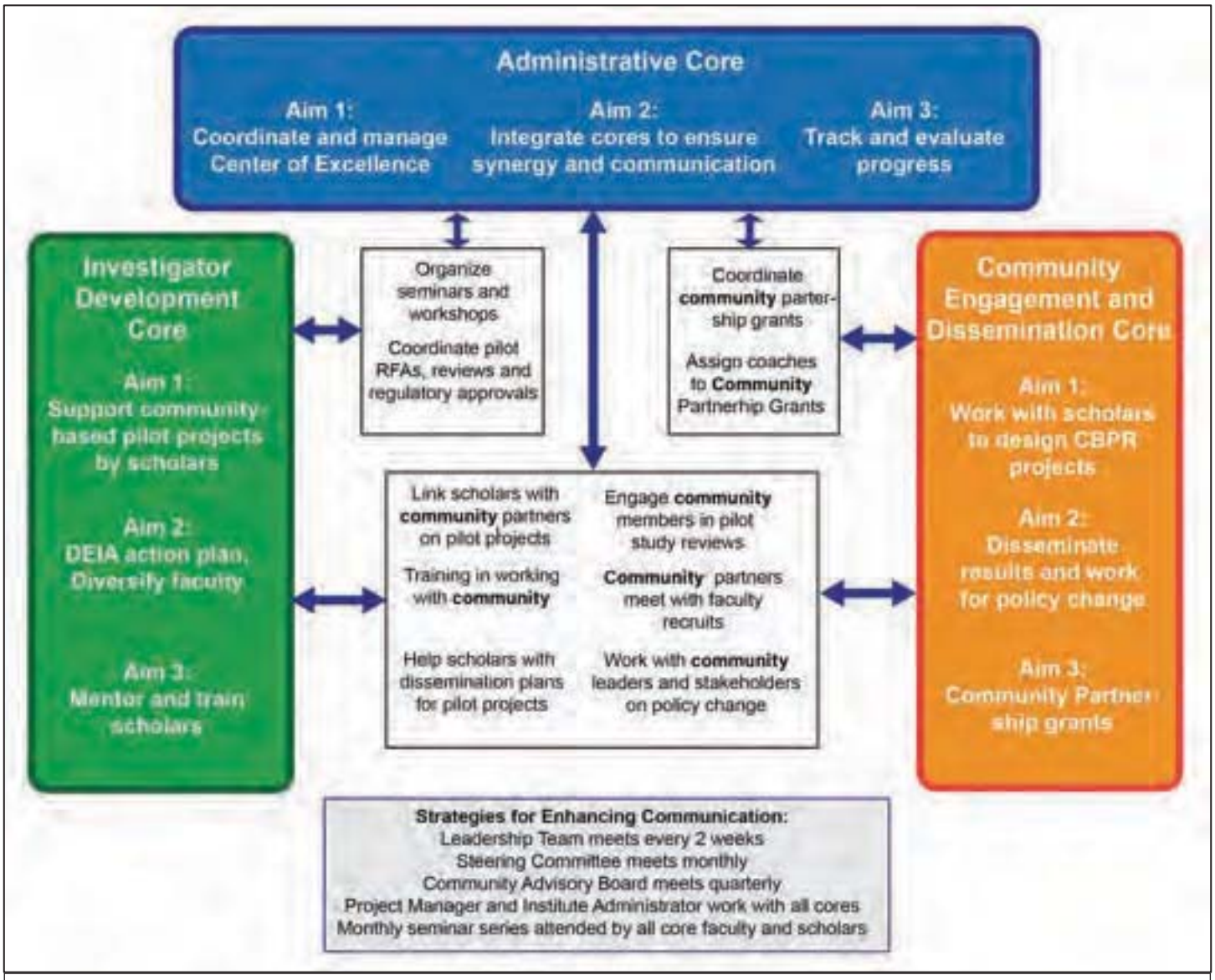


Figure A4. Coordination of Cores. DEIA: Dissemination, equity, inclusion, and accessibility; CBPR: community-based participatory research.

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.

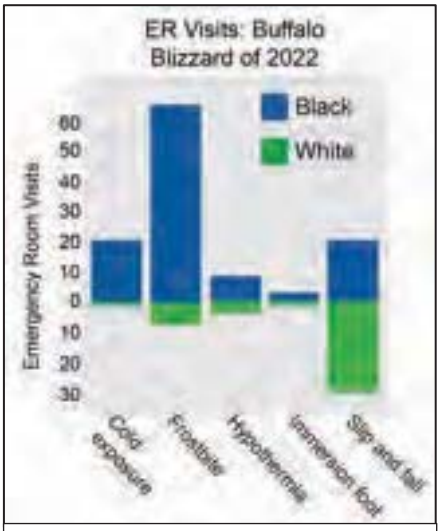


Figure A5. Race distribution of people who visited hospital ERs with cold-related injuries during the Blizzard of 2022.

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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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

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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

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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.

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Erie County Department of Health
Public Health
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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

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Change and Inspiration

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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:

Tracking Number: GRANT13951079 Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00

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-BEM Document 77-24 Filed 04/14/25 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)

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 174 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 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)

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 177 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 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)

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 180 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)	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)

Case 1:25-cv-10814-BEM Document 77-24 Filed 04/14/25 Page 183 of 375

Opportunity Number: RFA-MD-23-011 . Received Date: 2023-08-04T08:29:33.000-04:00