Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

APPENDIX - VOLUME III

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TABLE OF CONTENTS

ADDENDUM

Memorandum and Order on
Subject Matter Jurisdiction (25-cv-10814 Dkt. No. 105)..... A1

Memorandum and Order on
Motion to Dismiss (25-cv-10787 Dkt No. 84)..... A29

Transcript of Consolidated June 16, 2025, Bench Trial
(25-cv-10787 Dkt. No. 143) (25-cv-10814 Dkt. No. 156)..... A73

Partial Final Judgment 25-cv-10814
(25-cv-10814 Dkt. No.151)..... A161

Partial Final Judgment 25-cv-10787
(25-cv-10787 Dkt. No. 138)..... A163

Findings of Fact, Rulings of Law, and
Order for Partial Separate and Final Judgment
(25-cv-10787 Dkt. No. 151) (25-cv-10814 Dkt. No. 163)..... A166

Order Denying Motion to Stay Pending Appeal
(25-cv-10787 Dkt. No. 147) (25-cv-10814 Dkt. No. 160)..... A269

VOLUME I

Docket Report for *American Public Health Association, et al. v. National Institutes of Health, et al.*, Case No. 25-cv-10787 (APHA Case)..... A275

Docket Report for *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, Case No. 25-cv-10814 (States Case)..... A328

Complaint in APHA Case
(APHA Case Dkt. No. 1)..... A380

Amended Complaint in States Case
(States Case Dkt. No. 75)..... A458

Notice of Appeal APHA Case
(APHA Case Dkt. No. 139) A550

Notice of Appeal States Case
(States Case Dkt. No. 152) A553

NIH Review of Agency Priorities Based on the New Administration's Goals
February 12, 2025 (NIH_GRANTS_9) A556

Supplemental Guidance to Memo
February 13, 2025 (NIH_GRANTS_16) A557

Directive on NIH Priorities
February 21, 2025 (NIH_GRANTS_2930-31) A558

Award Assessments for Alignment with Agency Priorities
March 4, 2025 (NIH_GRANTS_2135-72) A560

Award Revision Guidance
March 13, 2025 (NIH_GRANTS_1957-58) A598

Award Assessments for Alignment with Agency Priorities
March 25, 2025 (NIH_GRANTS_3216-30) A600

Alignment with Priorities
May 7, 2025 (NIH_GRANTS_3547-81) A615

Alignment with Priorities
May 15, 2025 (NIH_GRANTS_3516-46) A650

Transcript of Consolidated May 8, 2025, Hearing
(25-cv-10814 Dkt. No. 107) A681

Transcript of Consolidated May 13, 2025, Hearing
(25-cv-10814 Dkt. No. 110) A709

Transcript of Consolidated June 3, 2025, Status Conference
(25-cv-10814 Dkt. No. 107) A740

VOLUME II - DECLARATIONS

Declaration Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-19	Declaration of Plaintiff Brittany Charlton	All.	A768
38-20	Declaration of Plaintiff Katie Edwards	1–13	A864
38-21	Declaration of Plaintiff Nicole Maphis	1–7	A876
38-22	Declaration of Plaintiff Peter Lurie	1–6	A883
38-23	Declaration of Georges C. Benjamin On behalf of Plaintiff American Public Health Association (APHA)	All.	A888
38-24	Declaration of Plaintiff Ibis Reproductive Health	1–10	A976
38-25	Declaration of Neal Sweeney On behalf of Plaintiff United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)	All.	A985
38-26	Declaration of Jeremy Berg	All.	A991
38-27	Declaration of Scott Delaney	All.	A1009
38-28	Declaration of APHA Member 1	1–10	A1091
38-29	Declaration of APHA Member 2	1–10	A1100
38-30	Declaration of APHA Member 4	1–9	A1109
38-31	Declaration of APHA Member 5	1–9	A1117
38-32	Declaration of APHA Member 7	1–24	A1125
38-33	Declaration of APHA Member 9	All.	A1148
38-34	Declaration of APHA Member 10	1–9	A1204

38-35	Declaration of UAW Pre-Member 1	1–7	A1212
38-36	Declaration of UAW Pre-Member 7	1–7	A1218
38-37	Declaration of UAW Member 3	1–8	A1224
38-38	Declaration of UAW Member 9	1–5	A1231
38-39	Declaration of UAW Member 10	1–8	A1235
38-40	Declaration of UAW Member 11	All.	A1242
38-41	Declaration of UAW Member 12	1–7	A1286
38-42	Declaration of UAW Member 13	1–5	A1292
72-3	Supplemental Declaration of Scott Delaney	All.	A1296
72-4	Supplemental Declaration of Jeremy Berg	All.	A1305
72-10	Supplemental Declaration of Plaintiff Nicole Maphis	1–3	A1316
72-12	Supplemental Declaration of Plaintiff Katie Edwards	All.	A1318
103-3	Second Supplemental Declaration Of Scott Delaney	All.	A1322
103-4	Second Supplemental Declaration Of Katie Edwards	All.	A1352

VOLUME III - EXHIBITS

Exhibits Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-01	NIH Webpage titled "Institutes at NIH"	All.	A1356

38-02	NIH webpage titled "Budget" (last updated on October 3, 2024)	All.	A1357
38-03	NIH webpage for Notice Number: NOT-OD-25-084, "NIH Operates Under a Continuing Resolution" (published April 3, 2025)	All.	A1360
38-04	Excerpt of NIH-wide Strategic Plan, Fiscal Years 2021-2025	All.	A1361
38-05	Excerpt of April 2024 NIH Grant Policy Statement	All.	A1405
38-06	March 14, 2025, Article from *The Atlantic* by Katherine J. Wu, titled "The NIH's Grant Terminations are 'Utter and Complete Chaos.'"	All.	A1424
38-08	Transcript of April 3, 2025, Deposition of Michelle Bulls in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 48-50, 68-76, 92-93, 99-102	A1439
38-09	Transcript of April 3, 2025, Deposition of Liza Bundesen in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 38-39	A1458
38-16	NIH Minority Health and Health Disparities Strategic Plan 2021-2025	All.	A1461
72-01	NIH webpage titled "Contracts"	All.	A1499
72-05	March 2025 Kirschstein NRSA Funding Opportunity	All.	A1506
72-06	January 2025 Kirschstein NRSA Funding Opportunity	All.	A1526
72-07	NIH webpage titled "Updates to NIH Institutional Training Grant Applications" (last updated March 25, 2025)	All.	A1542

72-08	March 11, 2025, Memo from Matthew Memoli with subject line "Initial Actions Regarding President Trump's Executive Orders – INFORMATION"	All.	A1550
72-09	April 8, 2021, Document Titled "Research General Terms and Conditions Agency Specific Requirements for the National Institutes of Health (NIH)"	All.	A1597
138-1	May 27, 2025, Spreadsheet of Grants	All.	A1603
138-2	June 13, 2025, Spreadsheet of Grants	All.	A1619

VOLUME IV - EXCERPTS FROM THE ADMINISTRATIVE RECORD

Excerpts from the Administrative Record
(from NIH_GRANTS_00001 to NIH_GRANTS_03578) A1636

VOLUME V - ADDITIONAL EXCERPTS FROM THE ADMINISTRATIVE RECORD

Additional Excerpts from the Administrative Record
(from NIH_GRANTS_03585 to NIH_GRANTS_05676) A2334

Case: 25-161 Case 1:25-cv-10787-BEM Document 38-1 Filed 04/25/25 Page 2 of 2 Case 1:25-cv-10787-BEM Document 38-1 Filed 04/25/25 Page 2 of 2 Entry ID: 6756750

NIH National Institutes of Health

INSTITUTES AT NIH

NIH is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems. NIH leadership plays an active role in shaping the agency's activities and outlook. Learn more about NIH.

List of Institutes and Centers

A listing of the institutes and centers that make up the NIH.

NIH Office of the Director

The central office at NIH responsible for setting policy and planning, managing, and coordinating NIH programs and activities.

Directors of NIH Institutes and Centers

The directors of the institutes, centers, and offices that make up the NIH.

NIH Institute and Center Contact Information

Contact information for the institutes, centers, and offices that make up the NIH.

NIH...Turning Discovery Into Health®

National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892

U.S. Department of Health and Human Services

A1356

Case: 25-161 Case 1:25-cv-10787-BEM Document 38-2 Filed 04/25/25 Page 2 of 4 Entry ID: 6756750

National Institutes of Health

WHAT WE DO

Budget

Research for the People

The NIH invests most of its nearly $48 billion budget[1] in medical research for the American people.

Nearly 83 percent[2] of NIH's funding is awarded for extramural research, largely through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state.

In addition, approximately 11 percent[2] of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland. The remaining 6 percent[2] covers research support, administrative, and facility construction, maintenance, or operational costs.

Justifications, Testimonies, and Appropriations

- Budget Requests — congressional justifications
- Congressional Testimony — budget requests & testimony by the NIH Director
- History of NIH Appropriations — from 1938

Funding for Diseases, Conditions, Research Areas

- Funding levels for diseases, conditions, and research areas, based on actual grants, contracts, research conducted at NIH, and other mechanisms of support.

Grants Awarded

- Funded Organization — universities and research organizations around the nation receiving research grants and contracts
- Budget and Spending — funding for grants and contracts
- Success Rates — annual percentage of research grant applications that are funded
- RePORTER — a searchable database of NIH-funded research projects

[1] Based on historical distribution of actual FY 2022 obligations across extramural and intramural mechanisms that comprise the annual NIH budget.

[2] Reflects the sum of enacted discretionary budget authority of slightly over $46.1 billion received under the Consolidated Appropriations Act, 2023 (P.L. 117-328). The budget total of $47.7 billion also includes $1.412 billion derived from PHS Evaluation financing, $141.5 million mandatory funding for the Special type 1 diabetes account, and $1.085 billion received from 21st Century Cures Act allocations. Appropriations received by the recently established Advanced Research Projects Agency for Health (ARPA-H) are excluded as is unobligated carryover related to emergency pandemic supplemental appropriations enacted prior to FY 2022 and resources from the HHS Nonrecurring Expenses Fund (NEF).

This page last reviewed on October 3, 2024

Impact of NIH Research

Case: 25-1611 Case 1:25-cv-10787-BEM Document 38-2 Filed 04/25/25 Page 3 of 4 Entry ID: 6756750

NIH research has had a major positive impact on nearly all of our lives by improving human health, fueling the U.S. economy, and creating jobs in our communities.

Read more »

Related Links

Office of Budget — NIH budget management, policy, planning, analysis, formulation and presentation

Office of Financial Management — provides leadership and direction for NIH financial management activities

Office of Extramural Research — provides guidance to NIH Institutes for research and training conducted outside the NIH

Office of Intramural Research — coordinates research conducted directly by NIH scientists

NIH Research Portfolio Online Reporting Tools — A one-stop shop for reports on the NIH research portfolio

A1358

Case: 25-1611 Case 1:25-cv-10787-BEM Document 38-2 Filed 04/25/25 Page 45 of 74 Entry ID: 6756750

NIH Operates Under a Continuing Resolution
Notice Number:
NOT-OD-25-084

Key Dates

Release Date:

April 3, 2025

Related Announcements

- January 10, 2025 - NIH Operates Under a Continuing Resolution. See Notice NOT-OD-25-054.
- October 10, 2024 - NIH Operates Under a Continuing Resolution. See Notice NOT-OD-25-010.

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

The Department of Health and Human Services (HHS), including National Institutes of Health (NIH), operates under the Full-Year Continuing Appropriations and Extensions Act, 2025 (Public Law 119-4) signed by President Trump on March 15, 2025. This Act (CR) continues government operations through September 30, 2025, at the Fiscal Year (FY) 2024 enacted level, with no reduction.

Consistent with NIH practices during FYs 2006 - 2024, NIH Institutes and/or Centers may, at their discretion, issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award. All legislative mandates that were in effect in FY 2024 (see NOT-OD-24-110) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see NOT-OD-24-057) and the Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees as described in NOT-OD-24-104.

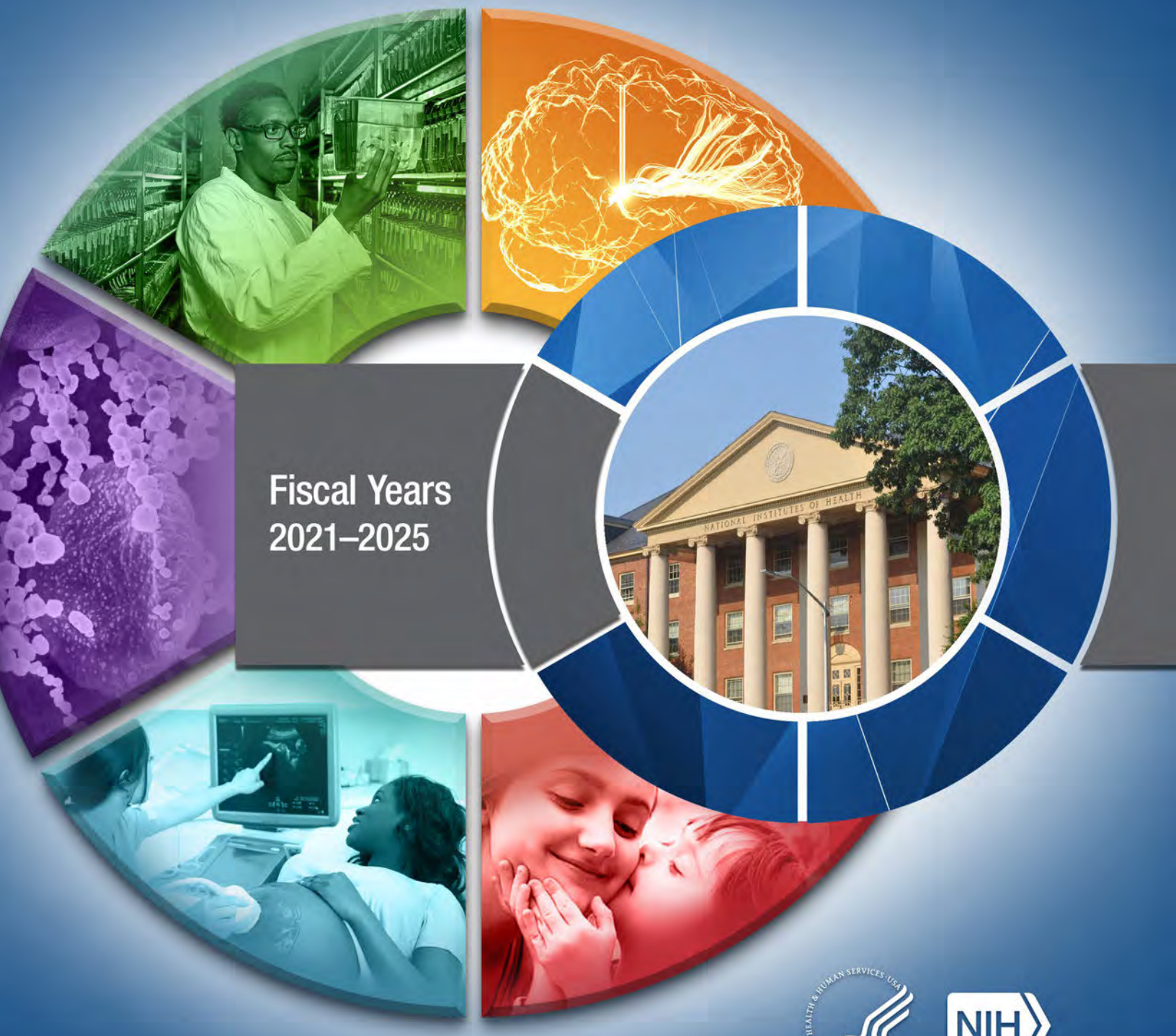
Inquiries

Please direct all inquiries to:

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified in the Notice of Award.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

NIH-WIDE STRATEGIC PLAN



Fiscal Years
2021–2025

A1361

Photo page ii: Cell-to-Cell Communication.
Credit: NCATS, NIH.

Photo page vi: Enzyme Repairing DNA.
Credit: Tom Ellenberger, Washington University School of Medicine in St. Louis, and Dave Gohara, Saint Louis University School of Medicine.

Photo page 41: Neurons.
Credit: Leterrier, NeuroCyto Lab, INP, Marseille, France.

Director's Message

To the American People,

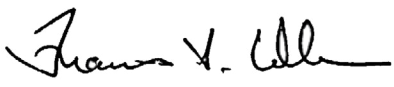
As our nation's biomedical research agency, the National Institutes of Health (NIH) has been the driving force behind many of the recent innovations in science and technology that are improving the health of all humankind. The coming years are certain to offer many exciting new opportunities for scientific exploration—and to pose some serious new challenges for human health. To rise to those opportunities and challenges, it is imperative that NIH, along with all sectors of society, work together in unprecedented ways with unprecedented speed.

Indeed, science is moving faster than ever before. To fuel this engine of discovery, NIH must continue to support the highest caliber research throughout the country and the world, while at the same time take vigorous steps to uphold the ethical conduct of science. NIH will further enhance the science of tomorrow by continuing its efforts to build a next generation of researchers that better reflects the rich, creative diversity of our great nation. The increasingly complex scientific questions that our society will face in the future will require not only diversity of scientific disciplines, but also diversity of thought, experience, and demographics.

As a publicly funded agency, NIH has a responsibility to be a good steward of the funds entrusted to us by the U.S. taxpayers. NIH will do this by investing efficiently and effectively in a wide range of basic, translational, clinical, and applied research, while at the same time supporting the workforce and infrastructure required for a sustainable research enterprise. As outlined in this Strategic Plan, this approach will enable NIH to build a solid foundation of fundamental knowledge about living systems that will serve to accelerate research aimed at addressing our most pressing health needs.

NIH's mission is to turn discovery into health. We thank you for your strong and steadfast support of this crucial mission, and we look forward to your continued support as we strive to use the power of science to create a healthier and more productive life for all.

With sincere appreciation,



Francis S. Collins
Director, National Institutes of Health

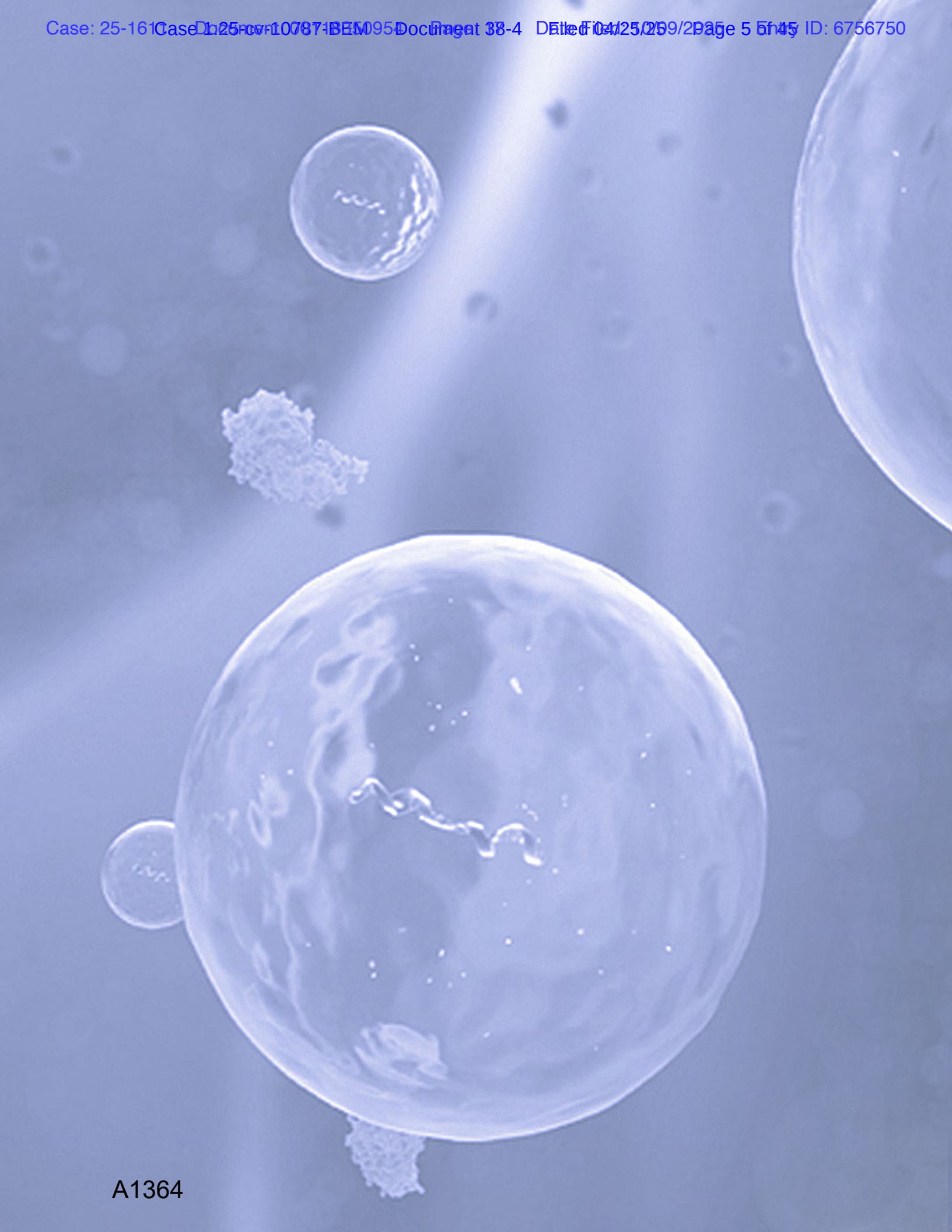


Table of Contents

Director's Message i

NIH-Wide Strategic Plan Framework vii

Overview of NIH 1

Mission and Goals 1

Organization 1

Supporting Researchers and Universities Through the Extramural Research Program 1

Research in Action in the NIH Intramural Research Program 2

Pioneering Clinical Research at the NIH Clinical Center 2

NIH's Strategy 3

Objective 1: Advancing Biomedical and Behavioral Sciences 3

Driving Foundational Science 3

Building Data Resources to Enable Research Progress 4

Inventing Tools and Technologies to Catalyze Discovery 6

Understanding Biological, Behavioral, and Social Determinants of Population Health 7

Preventing Disease and Promoting Health 8

Developing New and Improved Vaccines 8

Addressing Risk and Burden of Disease 9

Harnessing Technology to Inform Decision-Making 10

Designing Research for Everyone 11

Developing and Optimizing Treatments, Interventions, and Cures 11

Giving the Right Treatment to the Right Patient at the Right Time 12

Catalyzing Cell Engineering, Bioengineering, and Regenerative Medicine 13

Meeting Emerging Public Health Needs 14

Partnering to Advance Treatments and Cures 15

Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity 16

Enhancing the Biomedical and Behavioral Research Workforce 16

Supporting Research Resources and Infrastructure 18

Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science 20

Fostering a Culture of Good Scientific Stewardship 21

Setting Priorities 21

Monitoring Expenditures and Scientific Progress 21

Making Evidence-Informed Decisions 22

Assessing Programs, Processes, Outcomes, and Impact 22

Communicating Results 23

Leveraging Partnerships 24

Federal Partnerships 24

Public-Private Partnerships 25

International Partnerships 26

Public Engagement 26

Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences 27

Enhancing Reproducibility Through Rigorous and Transparent Research 27

Improving Stewardship of Clinical Trials 27

Assuring Ethical and Equitable Conduct of Research Through Inclusion 27

Maintaining Transparency Through Data Access and Sharing 28

Fostering a Safe and Harassment-Free Work Environment 28

Managing Risks to the Research Enterprise 29

Reducing Administrative Costs and Work Throughout the Grants Process 30

Optimizing Operations 30

Crosscutting Themes 32

Improving Minority Health and Reducing Health Disparities 32

Enhancing Women's Health 33

Addressing Public Health Challenges Across the Lifespan 33

Promoting Collaborative Science 34

Leveraging Data Science for Biomedical Discovery 34

Bold Predictions 35

References 37

Appendix I: NIH Statutory Authority 42

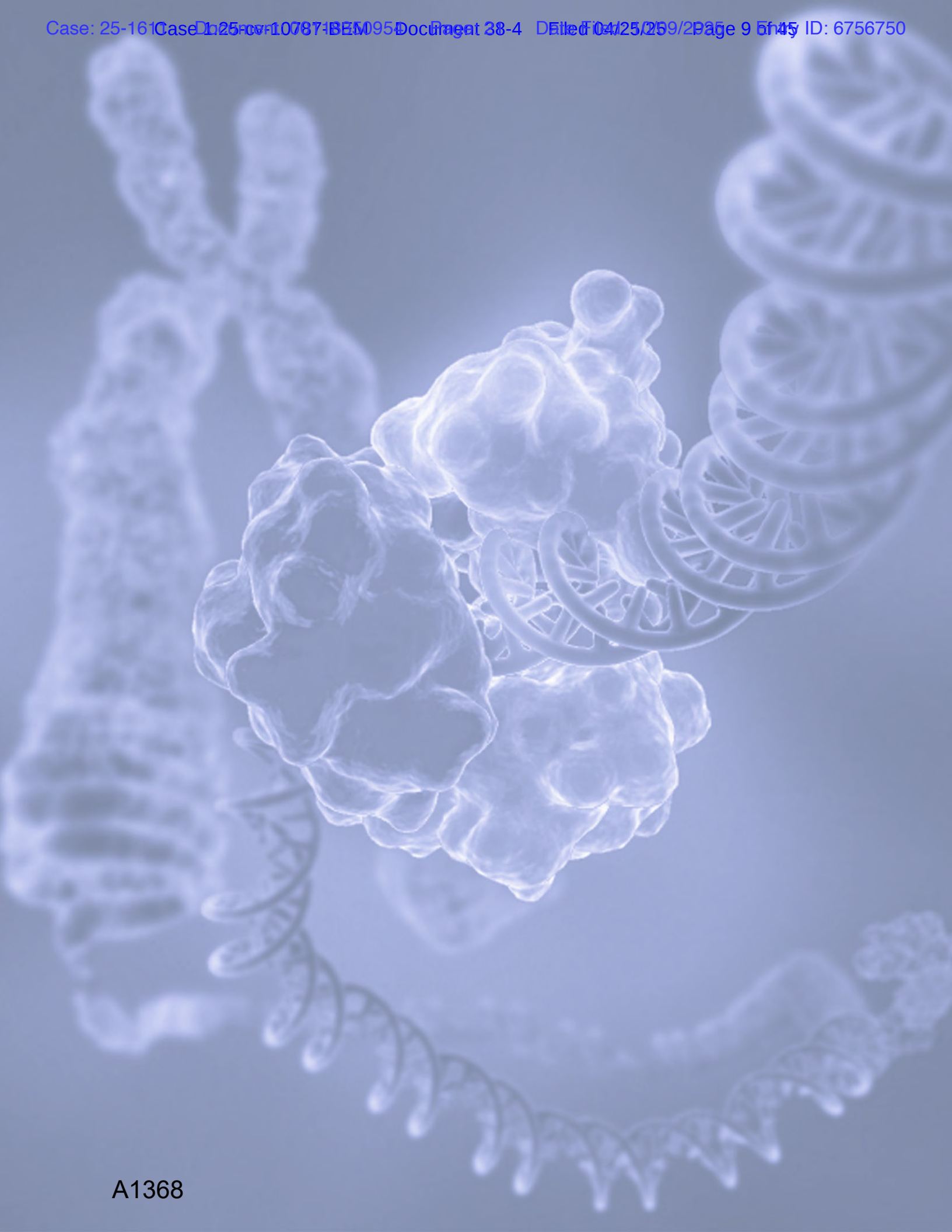
Appendix II: NIH Organizational Chart 43

Appendix III: Strategic Planning Process 44

Appendix IV: NIH Common Fund Strategic Plan Report 46

Appendix V: Acronyms 61

Acknowledgments 64



NIH-Wide Strategic Plan Framework

OVERVIEW OF NIH

MISSION:
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**

ORGANIZATION: 27 Institutes and Centers and the Office of the Director
- Extramural program: supporting research across the U.S. and beyond
- Intramural program: supporting research on NIH campuses

NIH'S STRATEGY

OBJECTIVES

Research Areas

Foundational Science

Disease Prevention and Health Promotion

Treatments, Interventions, and Cures

Research Capacity

Workforce

Infrastructure and Resources

Research Conduct

Stewardship

Partnerships

Accountability and Confidence

Management and Operations

CROSSCUTTING THEMES

NIH National Institutes of Health

Figure 1. NIH Main Campus

Credit: NIH.

The James H. Shannon Building (Building One) at the NIH main campus in Bethesda, MD.

Overview of NIH

Mission and Goals

At the National Institutes of Health (NIH), "Turning Discovery into Health" is what its tens of thousands of employees—and the hundreds of thousands of scientists it supports—strive to accomplish every day. As the foremost agency for funding biomedical research[a] in the U.S., NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and to use that knowledge to enhance health, lengthen life, and reduce illness and disability (Figure 1).[1] To achieve this mission, NIH works to support innovative research ultimately aimed at protecting and improving human health; train the biomedical research workforce and develop scientific infrastructure; contribute to the nation's economic growth by expanding the biomedical knowledge base; and promote integrity, public accountability, and societal responsibility in scientific research. As an operating division of the U.S. Department of Health and Human Services (HHS), NIH is responsible for carrying out the Department's goal of advancing scientific knowledge and innovation. NIH catalyzes life-saving research breakthroughs by providing critical funding to eligible research institutions throughout the nation and the world, and through the research conducted in NIH laboratories.

While NIH's primary mission is the conduct of research, the agency is also a trusted resource for accurate and timely biomedical information. NIH's biomedical information platforms are among the most visited websites in the federal government, giving researchers, health care professionals, and the public highquality information and data necessary to make informed decisions.

Organization

NIH is made up of 27 Institutes and Centers (ICs), and the NIH Office of the Director (OD).[2] Each IC has its own mission and research priorities focused on specific diseases, body systems, life stages, or fields of science. The NIH OD sets policy and provides guidance, in addition to serving as a resource for planning, managing, and coordinating the programs and activities of all of NIH.

NIH receives its annual funding, or appropriation, from the U.S. Congress. More than 80 percent of this funding is passed on to researchers and research institutions around the country—the extramural research community—through a rigorous, competitive process, while about 11 percent of NIH's budget supports intramural projects conducted by scientists in its own laboratories, which are subject to an equally rigorous review.[3]

Supporting Researchers and Universities Through the Extramural Research Program

Every year, NIH receives more than 54,000 research project grant applications[4] and funds almost 50,000 new and continuing grants. These grants support more than 300,000 researchers at all career stages, including more than 43,000 principal investigators at approximately 2,500 universities, medical schools, and other research institutions in every state of the U.S. and around the world. This enterprise is managed by NIH staff who facilitate and administer scientific programs, consult with scientific experts to inform priority setting, and act as agency experts for specific scientific areas.

NIH's funding decisions are made through a highly competitive, rigorous dual-level peer review process that emphasizes fairness and accountability and prioritizes support of the best scientific ideas.[5] NIH relies on the expertise of more than 25,000 external reviewers annually to assess the scientific merit of incoming grant applications in the first stage of peer review, which is followed by a second-level review for mission relevance by members of national advisory councils for ICs and the OD.[6] Final funding decisions are made by IC Directors, taking into consideration their IC's research program priorities in the context of the existing funding portfolio.

A variety of funding mechanisms—including grants, cooperative agreements, research contracts, prize competitions, and other less frequently used

[a] For the purposes of this Strategic Plan, the term biomedical is used broadly to include biological, behavioral, and social scientific perspectives.

mechanisms—are used to support NIH's broad scientific portfolio,[7] allowing maximum flexibility to fund the rapidly advancing needs of the biomedical research community. These mechanisms are used to support a wide range of efforts—from individual research projects, to international consortia and networks, to training opportunities—each of which may be tailored to meet specific goals. For example, to create innovative technologies that advance its mission and move them toward uptake in the market, NIH supports the Small Business Innovation Research and Small Business Technology Transfer programs.

Research in Action in the NIH Intramural Research Program

The NIH Intramural Research Program conducts NIH's in-house research and is the largest institution committed to biomedical and behavioral research, research training, and career development in the world.[8] The mission of the Intramural Research Program is to conduct distinctive, high-impact laboratory, clinical, and population-based research; facilitate new approaches to improve health through prevention, diagnosis, and treatment; respond to public health emergencies; and train the next generation of biomedical researchers. The program supports approximately 8,000 basic, translational, and clinical researchers at NIH research facilities located across the U.S., including the main NIH campus in Bethesda, Maryland; Research Triangle Park in North Carolina; Johns Hopkins Bayview Medical Center in Baltimore, Maryland; Frederick National Laboratory for Cancer Research in Frederick, Maryland; Rocky Mountain Laboratories in Hamilton, Montana; the Perinatology Research Branch in Detroit, Michigan; and the Phoenix Epidemiology and Clinical Research Branch in Phoenix, Arizona. Scientists in the Intramural Research Program include an estimated 1,200 principal investigators, 1,800 staff clinicians and staff scientists, and 5,000 trainees. Many important medical breakthroughs take place in the intramural research laboratories.

Pioneering Clinical Research at the NIH Clinical Center

The NIH Intramural Research Program includes the NIH Clinical Center,[9] the world's largest hospital devoted exclusively to clinical research. The NIH Clinical Center is designed to rapidly transition scientific observations and laboratory discoveries into clinical studies and bedside cures by bringing together talented investigators and specialized infrastructure, including unique patient cohorts, state-of-the-art equipment, and specialized services. Since its opening in 1953, more than half a million patients have been active partners with NIH in medical discovery. This partnership has resulted in a long list of medical milestones, including the development of chemotherapy for cancer; the development of some of the earliest artificial heart valves; the demonstration that lithium treats depression; and the first treatment of HIV/AIDS with azidothymidine.[10]

About 1,600 clinical research studies are in progress at the NIH Clinical Center. Approximately half are studies of the natural history of disease, while most of the other studies are clinical trials, often the first tests of new drugs and therapies in people. Participants come from all 50 U.S. states and around the world. With its unique ability to assemble cohorts of participants with rare diseases, the NIH Clinical Center plays an important role in fostering new multidisciplinary collaborations that study and find treatments for rare diseases, often revealing insights into common diseases, as well.

NIH's Strategy

To carry out its mission and optimize return on public investment, NIH has designed a strategic *Framework* that includes three key *Objectives* that align with the agency's goals. These three Objectives outline NIH's priorities in (1) biomedical and behavioral research areas, (2) research capacity, and (3) research conduct. Across all of these priorities, NIH emphasizes several *Crosscutting Themes*—approaches that are common to all Objectives of the Strategic Plan—including improving minority health and reducing health disparities; enhancing women's health; addressing public health challenges across the lifespan; promoting collaborative science; and leveraging data science for biomedical discovery. Examples of these important crosscutting topics are located throughout the three Objectives.

OBJECTIVE 1 Advancing Biomedical and Behavioral Sciences

The NIH portfolio is designed with the breadth and flexibility to address current public health needs, emerging areas of scientific opportunity, and public health emergencies, such as the coronavirus disease 2019 (COVID-19) pandemic (Figure 2). Over the next 5 years, NIH will drive cutting-edge biomedical and behavioral sciences forward on three interrelated fronts—foundational science, disease prevention and health promotion, and treatments, interventions, and cures.

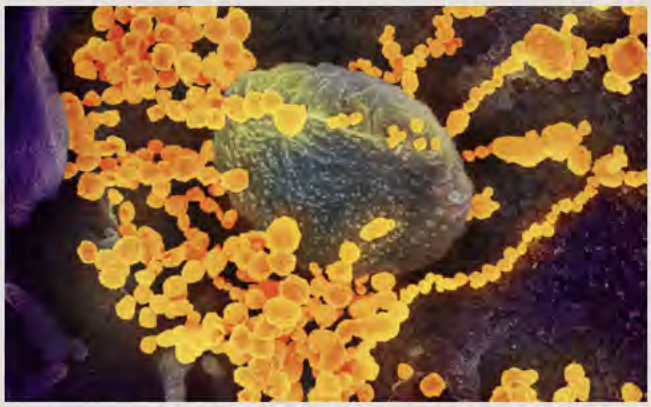
Driving Foundational Science

NIH supports a broad range of foundational scientific research to provide the building blocks for future diagnostics, treatments, and cures across the entire spectrum of health, diseases, and conditions, including those that are emerging, rare, or have yet to be discovered.

Foundational science includes basic biological, behavioral, and social research that generates the knowledge of how living systems work at the molecular, cellular, organismal, behavioral, and social levels.[11] Basic research can be experimental or observational and may involve manipulating molecules in test tubes and cells in culture dishes, studying animal models of disease (Figure 3), or conducting studies to understand human health and disease processes. Basic research also includes epidemiological studies

Figure 2. COVID-19 Research

Coronavirus disease 2019 (COVID-19) is an emergent human disease caused by a naturally arising novel coronavirus, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This scanning electron microscope image shows SARS-CoV-2 (round gold objects) emerging from the surface of cells cultured in the laboratory. NIH supports research to understand SARS-CoV-2 and mitigate the threat of COVID-19 for the health of all people by building on existing and accelerating the development of new research initiatives focused on five research priorities detailed in the *NIH-Wide Strategic Plan for COVID-19 Research*. NIH is improving basic understanding of SARS-CoV-2 and COVID-19 and developing the necessary tools and approaches to better diagnose, prevent, and treat this devastating disease. Pandemics recur, and NIH is also considering how to enhance preparedness for the next one.



Credit: Rocky Mountain Laboratory, NIAID, NIH.

to examine disease burden, distribution, and potential risk and protective factors in specific populations, as well as natural history studies that follow individuals over time to observe early stages and progression of a disease. NIH-supported research serves as the world's leading source of foundational knowledge of relevance to both the public and private sectors of biomedicine.[12]

Figure 3. Animal Research Models

Both people and animals have unique and important roles as research subjects. Many medical advances that enhance the lives of both humans and animals originate from animal studies. NIH supports research using a wide variety of animal models, from the familiar fruit flies, rodents, and nonhuman primates to more unexpected animal models, such as fish, frogs, and yeast. The types of animals used in research are chosen for their similarity to humans in anatomy, physiology, or genetics. For example, zebrafish (pictured) are frequently used in research because of their small size, rapid breeding, and transparent bodies. Approximately 70 percent of human genes are also found in the zebrafish, and zebrafish and humans share many critical developmental pathways. Not only can we learn how to prevent, treat, and cure human diseases by studying animals, but often the treatments developed can also be used to improve the health of animals. In addition, NIH is acting to reduce the number of animals needed for research by using other approaches, such as tissue chips.

Credit: Grimes DT, Boswell CW, Morante NF, Henkelman RM. Used with the permission of Rebecca D. Burdine, Ph.D.

Much of the research process is carefully planned and conducted, but serendipitous discoveries can also drive progress. Because science explores the unknown, it is not always possible to predict where research will lead. This concept is especially true for basic research, which integrates biology, behavior, environment, medicine, physics, chemistry, engineering, and data science to pioneer novel technologies capable of exploring the individual components of life. Investments in basic science result in unexpected breakthroughs and new fields of inquiry that could not have been envisioned when the original experiments were designed. For example, scientists leveraged the discovery of the CRISPR system, a component of the bacterial immune system that responds to viral infection, to develop a molecular tool for editing genes with exquisite precision. This technology has revolutionized the ability to study genes and holds great promise for treating numerous genetic disorders. By investing in foundational science, NIH is laying the groundwork for important future advances that will improve the nation's health.

Building Data Resources to Enable Research Progress

NIH supports the creation of foundational data resources that enable basic research and improve understanding of the biological and environmental factors that contribute to human health and disease. NIH achieves this effort by funding investigators who are studying and cataloging molecules that are the basic building blocks of life—such as DNA, RNA, and proteins—as well as researchers who are establishing and collecting data from large cohorts of research participants. The resulting datasets have the potential to catalyze whole fields of research, as well as lead to the development of new diagnostic tools and therapies.

The 21st century opened with a crowning achievement of basic science, sequencing the human genome—the complete collection of genetic information within an individual. This achievement became the foundation for the branch of science that studies genomes across individuals to find patterns in health and disease and to uncover mechanisms to understand how genes interact with one another and with a person's environment. The immense amount of data produced by genomic studies is helping researchers understand how the complex interactions among different regions of the genome influence human development, aging, and health. One major genomic data resource is the ENCyclopedia of DNA Elements (ENCODE), which is aimed at identifying the function of all parts of the human and mouse genomes and has already been cited by thousands of research publications.[13] The Clinical Genome (ClinGen) Resource catalogues the physical, clinical, and genetic characteristics of individuals to better understand how small changes, or variants, in a person's genome are related to their health.[14] NIH will continue to support the expansion of these databases and improvement of the tools researchers use to generate and analyze genomic data through the development of new DNA-sequencing technologies and computational methods. NIH will also support new efforts to ensure the inclusion of genomes of individuals from

groups that have been historically underrepresented in genomics research.[15]

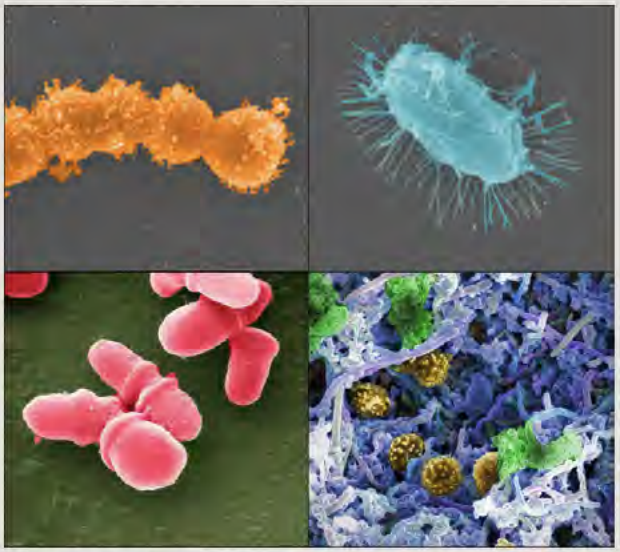
Harnessing the power of DNA-sequencing technologies, NIH-funded scientists have also created fundamental datasets important to microbiome research, or the study of the microbes—including bacteria, viruses, and fungi—that live on and in the human body. The average healthy adult is host to trillions of microbes that live in the gut, in the mouth, or on the skin, for example. The composition of the microbiome influences human health and response to treatment, contributes to early development, affects the immune system, and plays a role in metabolism. The NIH Common Fund's[b] Human Microbiome Project (HMP), conducted from 2007 to 2016, was the first large-scale effort to map and identify the thousands of species of microbes in the human microbiome (Figure 4).[16] HMP generated a comprehensive profile of the microbiome from multiple body sites from more than 300 healthy people and created computational tools and resources to enable more research. HMP also collected microbiome and human data from three longterm cohort studies centered on pregnancy and preterm birth, inflammatory bowel disease, and type 2 diabetes.

Ongoing studies supported by NIH are investigating how the microbiome of pregnant women may affect the risk of preterm birth;[17] exploring the possibility of using complementary foods—foods given in addition to those regularly consumed in the diet—to boost the gut microbiome and treat childhood malnutrition;[18] understanding how beneficial microbes in the mouth protect against periodontal disease or other oral infections;[19] and uncovering how the microbiome influences cancer development and response to therapy.[20] One particularly promising area of research is exploring the role of the microbiome in the onset of chronic conditions involving immune system dysfunction, such as cardiovascular disease and inflammatory diseases of the gut.[21]

Studies that generate large datasets from diverse participants provide vital fundamental research resources. The Adolescent Brain Cognitive Development (ABCD)[22] study is the largest long-term study of brain development and child health in the U.S. This study has recruited more than 11,000 children 9 to 10 years of age, who will be followed into adulthood to explore how childhood experiences affect brain development and a variety of health-related outcomes. Data collection is ongoing, and researchers from within and outside the ABCD study are using the data generated to conduct research on such topics as the link between screen time and brain structure,[23] effects of prenatal exposure to cannabis use,[24] and the relationship between sleep and brain structure and function.[25]

Figure 4. Human Microbiome Project

The Human Microbiome Project, which was launched by NIH in 2007, provided the first glimpse of the microbial diversity of healthy humans and is exploring the possible relationships between particular human diseases and the microbiome.



Credits: Composite image, Jonathan Bailey, NHGRI, NIH. Individual images (Clockwise from top left), Streptococcus, *Tom Schmidt; microbial biofilm of mixed species, from human body, A. Earl, Broad Institute/ Massachusetts Institute of Technology;* Bacillus, *Tom Schmidt;* Malassezia lopophilis, *J.H. Carr, CDC.*

Many NIH-funded projects span multiple areas of research and include both basic and applied science. The ambitious Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative aims to answer fundamental questions about how brain circuits work; how they become impaired in neurological, psychiatric, and substance use disorders; and how to improve the function of these circuits to treat brain disorders (Figure 5).[26] Components of the BRAIN Initiative® include studies to record, image, and manipulate brain circuits with the aim of developing treatments for brain disorders; development and dissemination of informatics tools to allow

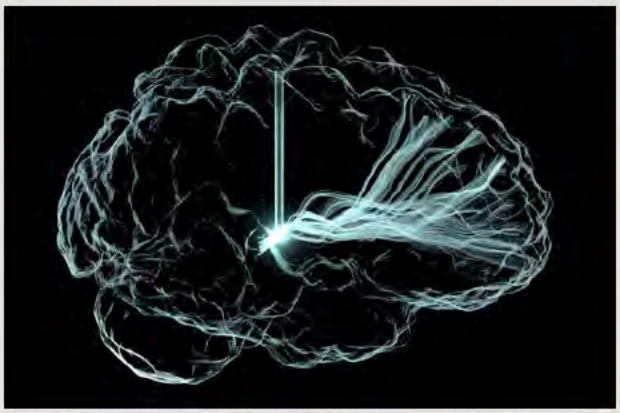
[b] For more information on the NIH Common Fund, see Appendix IV.

widespread sharing and interpretation of research data; and efforts to discover and catalogue the multitude of types of brain cells.

The complexity of the nearly 170 billion cells in a human brain presents a formidable challenge to understanding how different cell types work in brain circuits, their role in disease, and how they might be targeted directly by new therapies. Advances in engineering and highthroughput methods to classify individual cell types have enabled new opportunities to tackle this challenge. The BRAIN Initiative® Cell Census Network is developing a comprehensive mouse brain cell atlas and applying cell type identification methods to studies of human brain tissue.[27]

Figure 5. BRAIN® Initiative

First-place photo winner from the Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative's 2019 "Show Us Your Brains" photo and video contest for BRAIN investigators. "Light Me Up!" is a light-based rendering of deep brain stimulation's electrical excitation of neuronal fiber pathways to treat patients who have traumatic brain injury.



Credit: Andrew Janson, Graduate Student Research Assistant, Scientific Computing and Imaging Institute, The University of Utah.

Scientists have begun to use these methods to determine precisely which human brain cells are affected in a range of conditions, including Alzheimer's disease and related dementias, autism spectrum disorder, and Zika virus infection.

Inventing Tools and Technologies to Catalyze Discovery

Fundamental research includes the creation of advanced biomedical research tools and technologies for scientists to answer questions about biology and human health. For example, imaging technology has transformed science, allowing researchers to "see" individual molecules interacting, measure brain function, study internal tissues, visualize cell functioning in 3-D in real time, and locate specific molecules in the body using chemical tags.

Certain NIH programs are initiated specifically to spur the development of new tools and technologies for research use. The NIH Common Fund's Single Cell Analysis Program (SCAP) focused on developing tools to explore the behavior of single cells, including new ways to track cells in living multicellular organisms, new imaging techniques and technologies, and sequencing of the genome and transcriptome—the collection of all gene readouts present in a cell.[28] Resources developed through SCAP have paved the way for research that may lead to breakthroughs in understanding the human body at the level of individual cells, rather than groups or populations of cells. Such resources include the NIH Common Fund's Human BioMolecular Atlas Program (HuBMAP), a collaborative effort to develop a global open platform to map the approximately 37 trillion cells in the human body to understand how the relationships between cells can affect a person's health.[29]

New technologies are yielding data in quantities and at a level of complexity that requires increased capacity for storage, management, and analysis. Artificial Intelligence (AI) is being used on big datasets to augment human ability to detect patterns and predict outcomes, thus offering significant promise to advance research. NIH will build a large and diverse set of programs to foster machine learning (a subset of AI), support the generation and management of large-scale datasets, convene multidisciplinary teams of researchers, and develop a set of ethical principles for NIH-funded researchers to follow when using AI (Figure 6).[30] Advances in data science facilitate data processing and sharing, but concomitantly raise concerns regarding privacy, security, ethics, and bias. NIH is proactively engaging data and computer scientists, engineers, clinicians, research participants, ethicists, and the public in its plans to address future challenges and opportunities.

Studies are beginning to demonstrate the potential AI has for revolutionizing medical practice. For example, NIH researchers developed a novel data-driven approach for automated diagnosis and prognosis of Age-related Macular Degeneration (AMD), highlighting the potential of these systems to assist early disease detection and enhance clinical decision-making

Figure 6. ELSI Research at NIH

The term *ELSI* refers to the consideration of Ethical, Legal, and Social Implications of research, particularly in emerging biomedical fields; ELSI has its roots in the genomics community, but has expanded to include other areas of NIH research. ELSI complements scientific research by identifying, analyzing, and addressing the ethical, legal, and social implications of research as it is being conducted. NIH supports ELSI research to facilitate the responsible integration of science into society. Today ELSI initiatives are underway across NIH in several areas of biomedical and behavioral research, such as neuroscience, epidemiology, environmental health, new and emerging technology development and use, precision and personalized medicine, clinical research and care, and special and vulnerable population research. Key to NIH's approach to ELSI is collaboration with its multiple stakeholders.

processes.[31,32] The U.S. Food and Drug Administration (FDA) also approved the first automated medical device to use AI to detect diabetic retinopathy.[33] NIH will continue to explore and expand further uses of AI.

Understanding Biological, Behavioral, and Social Determinants of Population Health

Building the foundation for science includes constructing an overall picture of how physiological, behavioral, and social factors alone and in combination may determine human health. Conditions in which an individual is born, lives, learns, works, and ages combined with the behaviors that they engage in can affect a wide range of health outcomes.[34] Understanding how these factors interact with an individual's biological make-up is a vital area of research. The epigenome consists of chemical compounds and proteins that can attach to DNA and turn genes on and off. These changes in gene expression can occur in response to social experiences (both positive and negative) and environmental exposures and may be passed from one generation to the next. NIH supports research on social epigenomics, the study of how social experiences throughout a person's lifetime can affect biology and health status through changes to the epigenome. Similarly, NIH supports research on environmental epigenomics, which looks at how an individual's exposure to factors in the physical environment—such as air, water, and soil—may also impact gene expression. Studies designed to elucidate how social experiences and environmental exposures—such as those experienced through structural racism and lower economic status—affect the individual epigenome among racial and ethnic groups can provide a unique opportunity to identify the changes that occur within and between populations. This knowledge can be used to increase understanding of minority health and decrease health disparities.

Social and behavioral research is crucial to understanding the health and developmental effects of using digital technology and electronic media that have become integral parts of daily life. Findings from the ABCD study and the NIH Intramural Research Program have demonstrated that a significant proportion of children across a wide age range exceed the daily limits on screen time recommended by the American Academy of Pediatrics.[35,36] In light of the COVID-19 pandemic, screen time has dramatically increased for children of all ages, the effects of which will need to be investigated. To assess how technology and media use affect early childhood health and development—as well as the nature of social interactions among families, peers, and society—NIH will support an initiative to study the impact of technology and media exposure on early childhood development and health outcomes. This effort will support coordinated research projects using existing and newly collected data, as well as determining measures for exposure, usage, development, and health outcomes, including neuroimaging, language development, physical activity, and hormone levels.

Integrating different types of research to address health needs for specific populations can improve the health of these populations and also provide insights into common conditions. For example, Down syndrome is the most common genetic disease of mild to moderate intellectual disability, occurring in 1 out of every 700 babies born in the U.S. In 2018, NIH launched the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) project, which studies conditions that affect the general population and often co-occur (i.e., are comorbid) with Down syndrome, such as Alzheimer's disease and related dementias, autism, cataracts, celiac disease, cardiovascular disease, and diabetes (Figure 7). The program focuses on targeted, high-risk/high-reward basic science studies on the causes of Down syndrome comorbidities, cohort studies of individuals with Down syndrome, and inclusion of individuals with Down syndrome in new and existing clinical trials.

Understanding the fundamental processes underlying human health is a key step in determining how to promote and restore health and identify, prevent,

and treat disease. Over the next 5 years, NIH will continue to invest in fundamental research projects that provide new insights into basic biological, behavioral, and social processes across the spectrum—from molecules to cells to humans to communities. These investments will undoubtedly lay the groundwork for unimaginable breakthroughs that will lead NIH one step closer to improving human health.

Figure 7. INCLUDE Project

The INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) project is an NIH-wide research initiative involving 18 Institutes and Centers that aims to understand critical health and quality-of-life needs for individuals with Down syndrome. Down syndrome is the most common genetic cause of mild to moderate intellectual disability and occurs in one out of every 700 babies born in the U.S.

Credit: The INCLUDE Project, NIH.

Preventing Disease and Promoting Health

Disease prevention and health promotion are core components of NIH's research mission to improve the health of all Americans. NIH research strengthens the evidence base on which national public health objectives and related disease prevention and health promotion strategies are built. Prevention research targets biological, social, and environmental factors, individual behaviors, and health services and informs health-related guidelines, policies, and regulations. NIH supports a broad portfolio of research that examines the best way to bring effective disease prevention and health promotion strategies into communities.

Developing New and Improved Vaccines

Vaccines provide a safe, cost-effective, and efficient means of preventing illness, disability, and death from infectious diseases. NIH supports a comprehensive spectrum of immunology and infectious disease research focused on developing improved or novel vaccines. This includes study of pathogen–host interactions and technological advancements in vaccine development that have led to innovative and exciting vaccine research strategies. For example, NIH-supported researchers are working to identify new platforms to deliver vaccine components and explore how adjuvants (i.e., vaccine components that enhance the immune response) affect the potency, durability, and other aspects of vaccine-induced immunity.[37]

An important remaining need is the rapid development of new vaccines to mitigate emerging infectious disease outbreaks, such as COVID-19, Ebola virus disease (EVD), and influenza (flu). NIH, in collaboration with its industry partner, developed an experimental vaccine for COVID-19 in just weeks using the genetic sequence of SARS-CoV-2 (i.e., the virus that causes COVID-19).[38] As of late 2020, the vaccine co-developed by scientists at NIH and Moderna was granted an Emergency Use Authorization by the FDA, after rigorously testing its safety and ability to protect against infection. Other vaccines are still being tested.[39] Recent outbreaks of the Ebola virus spurred the development of multiple vaccine candidates for EVD, including the rVSV-ZEBOV vaccine, which through significant federal government support was brought to market by the private sector, licensed in 2019, and is now widely available.[40] Preliminary data from an outbreak in the Democratic Republic of the Congo (DRC) has shown that this vaccine is highly effective in preventing disease and death.[41] In the U.S., seasonal influenza causes 12,000–61,000 deaths annually,[42] and emerging influenza strains pose a pandemic risk. A key focus of the NIH influenza research program is developing a universal vaccine[43] that provides robust, long-lasting protection against multiple subtypes of influenza (Figure 8), eliminating the need for a seasonal flu vaccine each year and providing protection against newly emerging strains with pandemic potential. Several flu vaccine clinical trials are being conducted, including an NIH-sponsored trial of a universal vaccine candidate that uses a nanoparticle technology to display portions of the influenza virus that are the same or very similar among different influenza strains.[44]

A1378

Figure 8. Universal Flu Vaccine

A healthy volunteer receives an experimental universal influenza vaccine known as H1ssF_3928 as part of a Phase 1 clinical trial at the NIH Clinical Center in Bethesda, Maryland. Scientists at the Vaccine Research Center developed the vaccine.

Credit: NIAID, NIH.

In addition to furthering the development of vaccines against specific pathogens, NIH supports the development of technologies that enable scientists to apply a standardized manufacturing process to develop candidate vaccines against various pathogens and create a collective database with information on their safety. This streamlined approach can shorten the preclinical development period from years to months and is important for rapid response to emerging infectious disease threats.

Addressing Risk and Burden of Disease

NIH is committed to supporting research to reduce the impact of disease by identifying and improving understanding of risk factors (e.g., inadequate nutrition, low physical activity, built environment, tobacco use, alcohol or drug misuse) and protective factors (e.g., weight management, regular exercise, daily tooth brushing and flossing) alone and in combination with genetic factors. An important goal of prevention is to alter the balance between risk and protective factors so that protective factors outweigh risk factors. Screening, health promotion, counseling, behavioral change, stress management, and preventive medications are all potential strategies for reducing individual risk. NIH investments have helped lead to advances in screening for cardiovascular disease, lung cancer, abnormal blood glucose, type 2 diabetes, oral cancer, and intimate partner violence, as well as interventions to address obesity and tobacco use in children and adolescents.

One example of NIH's investments in risk identification is in suicide prevention (Figure 9). Suicide remains one of the top 10 leading causes of death in the U.S., claiming the lives of more than 48,000 people each year.[45] Although it impacts all ages and in all parts of the country, some specific groups are disproportionately affected, such as sexual and gender minority (SGM) populations (especially transgender and gender non-conforming youth) and American Indian or Alaska Native populations (who have the highest suicide rates of any racial or ethnic group in the U.S.[46]). NIH-supported suicide prevention research illustrates how improvements in care can save lives. Universal screening for suicide risk in emergency departments has been shown to be effective and feasible.[47] Building on these findings, NIH-supported researchers are testing brief interventions and follow-up care to prevent recurring self-harm and related comorbidities, such as substance use disorder.

NIH-supported studies have demonstrated how long-term, multigenerational studies of chronic diseases can give rise to innovative prevention and intervention strategies. For example, the Framingham Heart Study,[48] launched in 1948, continues to inform tobacco cessation, nutrition, physical activity, and blood pressure control strategies that are used all over the world to reduce the risk of chronic disease. High blood pressure, or hypertension, is common over the age of 50 years and is a leading risk factor for cardiovascular diseases like heart disease and stroke. It may also increase the risk of dementia later in life. Data from several NIH-funded observational studies suggested that cardiovascular disease risk increases when systolic blood pressure rises beyond a certain level. NIH's Systolic Blood Pressure Intervention Trial (SPRINT)[49] assessed whether aggressively lowering blood pressure can prevent these conditions. SPRINT found that maintaining systolic blood pressure at less than 120 mm Hg reduced the combined risk of heart attack, heart failure, and stroke by 25 percent and reduced the risk of death by 27 percent compared to the standard blood pressure target at the time (140 mm Hg).[50] These findings helped change the national guidelines for treating hypertension, which now use 120 mm Hg as the standard blood pressure target.[51] If successfully adopted into clinical practice across the U.S., these guidelines are expected to prevent about 107,500 deaths per year among people at high risk for fatal cardiovascular disease.[52]

Figure 9. Suicide Prevention

"Five action steps for helping someone in emotional pain": Infographic.

Credit: NIMH, NIH.

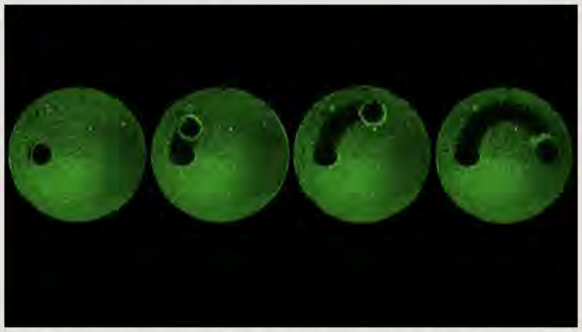
Harnessing Technology to Inform Decision-Making

NIH supports the development of new or improved interventions and technologies along with repurposing existing technologies to monitor and reduce disease risk, enhance protective factors, and restore health (Figure 10). Coupled with advances in data science that enhance analytical capacity and speed, these technologies and tools will help aid decision-making by patients and providers and improve disease prevention and health promotion strategies at the individual, family, community, and population health levels.

Most information used to make decisions in current medical practice is collected at a specific moment in time and in a clinical setting, such as taking blood pressure, providing a limited view of an individual's health and disease risk. Heart rate and motion sensors in smart watches and other wearable devices are examples of consumer technologies that can provide continuous feedback to help people improve their health. These devices detect underlying signs of illness and response to interventions, including medications and lifestyle changes, faster than conventional methods that often require weeks or months to provide actionable feedback. NIH-supported researchers have developed a wearable sensor made of stretchable microelectronics that uses ultrasound to measure blood pressure continuously, whether the wearer is resting or active. Such devices may help identify people at risk of stroke and heart disease by

Figure 10. Nanorobots for Dental Health

NIH supported a collaboration among biomedical researchers and engineers to build microscopic nanorobots to target, destroy, and remove dental plaque, a harmful community of bacteria that grow on teeth. The nanorobots, which contain an antibacterial compound, are controlled using tiny magnets to perform micro-scale precision cleaning, including hard-to-reach spaces. This technology could be used to prevent dental caries and periodontal disease, in addition to cleaning other surfaces susceptible to biofilms, such as metal implants and catheters or hospital equipment.



Credit: Geelsu Hwang and Edward Steager, University of Pennsylvania.

providing patients and physicians with more frequent and accessible information on blood pressure, including fluctuations that occur during the wide variety of activities that people engage in every day.[53]

Designing Research for Everyone

NIH prioritizes research that addresses the needs of underserved populations to address the factors that contribute to health disparities. NIH-wide efforts will continue to focus on developing and testing interventions to reduce health disparities, identifying key gaps in prevention science related to health disparities, and promoting targeted research on appropriately tailored public health, clinical, and community preventive services in diverse settings and contexts. For example, the NIH *All of Us* Research Program[54] has been designed to reflect the diversity of the U.S., with a special focus on including participants from groups that have been underrepresented in health research (Figure 11).

The Collaborative Minority Health and Health Disparities Research with Tribal Epidemiology Centers initiative supports research on topics related to minority health and health disparities in American Indian or Alaska Native populations, with emphasis on areas where there are significant gaps in data and knowledge. Current research projects include examining the impact of the Navajo Nation Tax on Junk Food on health outcomes, identifying the incidence and prevalence of arthritis and autoimmune disease among Alaska Natives, and understanding determinants of motor vehicle injuries and deaths among the Northwest Tribes.[55]

Sex and gender also influence health and disease. *Sex* refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. *Gender* refers to socially constructed and enacted roles and behaviors, which occur in a historical and cultural context and vary across societies and over time.[56] Considering the effects of sex and gender in study design, data collection and analysis, and dissemination of findings will help to inform the development of prevention strategies and interventions for everyone.

Developing and Optimizing Treatments, Interventions, and Cures

Building on the solid foundation of fundamental discoveries in biology, health and disease, and behavior, as well as innovations in data science and emerging technologies, NIH-supported scientists continue to develop new and improved treatments and cures, including for diseases that were considered intractable even a decade ago.

The path to a new treatment often begins not in the clinic or community but in the laboratory, where basic researchers refine our understanding of disease and identify aspects of disease causation or progression

Figure 11. *All of Us* Research Program

The NIH *All of Us* Research Program is a historic effort to collect and study data from 1 million or more people living in the U.S. The program's goal is better health for all of us, and its aim is to gather data on genetics, lifestyle, and environmental exposures. The *All of Us* Research Program is unique because it is disease agnostic, meaning that it will not focus on one disease, risk factor, or group of people, instead enabling researchers to evaluate multiple risk factors that are associated with outcomes across different diseases. This unprecedented scientific resource will enable research on numerous diseases and conditions across populations and the lifespan, with a special focus on outreach to groups that have been underrepresented in health research, to reflect the diversity of the U.S. The *All of Us* Research Program has already begun to make an early, non-finalized version of its Researcher Workbench available, an important milestone toward creating a publicly accessible platform to increase research on understudied areas, including wellness and resilience.

Credit: NIH.

that could be targeted therapeutically. Investigators use this information to design candidate treatment approaches using cell or tissue samples, animal models, or computer simulations. If the candidate approaches appear to be safe and effective in this preclinical setting, they are moved into human trials, where they are tested for safety and efficacy. Finally, new and improved methods to promote the adoption of effective and proven interventions are identified and refined through implementation research. This process is rarely straightforward. In fact, sometimes the process even circles back on itself in a "virtuous cycle," with applied research informing new ideas in basic research.

To illustrate, NIH-supported basic science was a springboard for the development of a ground-breaking new cystic fibrosis treatment. Cystic fibrosis is an inherited disorder that causes mucus to accumulate in the airways and digestive tract. The identification of the *CFTR* gene, which is mutated in affected individuals, along with additional discoveries over several decades, has enabled a variety of progressively more effective drug therapies for the disease. Recent NIH-supported clinical trials demonstrated that a novel triple-drug therapy could compensate for the effects of a *CFTR* mutation that occurs in 90 percent of affected individuals.[57] Now, instead of being a fatal disease, there is promise that cystic fibrosis in many individuals could soon be a chronic condition that can be managed over a long lifetime.

NIH supports randomized controlled clinical trials—studies conducted under "ideal" research conditions in which participants are randomly placed into one of two or more groups that receive different interventions or a placebo (i.e., a treatment with no therapeutic effect). Outcomes from each group are then analyzed and compared. Such studies are considered the gold standard by which clinical researchers determine the safety and effectiveness of interventions. NIH also supports pragmatic trials, which are designed to evaluate interventions in real-world settings and situations. To support and facilitate pragmatic trials, NIH established a Health Care Systems Research Collaboratory[58] under the NIH Common Fund to engage with health care delivery organizations as key research partners. The Collaboratory disseminates best research practices, provides education and coordination, and supports pilot projects involving a variety of diseases and conditions in community settings.

Giving the Right Treatment to the Right Patient at the Right Time

Advances in molecular medicine have allowed health professionals to move toward a precision medicine approach for targeted treatment and prevention that considers an individual's genes, environment, and lifestyle. In contrast to a one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, precision medicine will allow doctors and researchers to predict more accurately which treatment and prevention strategies will work best in an individual. Unlike research studies that focus on one disease, risk factor, or group of people, the *All of Us* Research Program is building an unprecedented scientific resource that will enable research on numerous diseases and conditions across populations and the lifespan.

Patients with certain types of cancer are already benefiting from precision medicine approaches. For example, an NIH-supported clinical trial showed that a molecular test for the expression of 21 genes associated with breast cancer recurrence could determine whether patients with the most common type of breast cancer would benefit from chemotherapy in addition to surgery.[59,60] The researchers found that most of these women can safely avoid chemotherapy and its toxic side effects.

The promise of precision medicine is exemplified by the development, built on decades of research, of new therapies that harness patients' own immune systems to attack their cancer. Among them are chimeric antigen receptor (CAR) T-cell therapies that are made by genetically engineering a patient's own immune cells so they will bind to specific proteins on cancer cells and kill them. Approved by the FDA in 2017, these biologic products have resulted in remarkable benefits to children and adults with certain types of leukemia and lymphoma.[61] Unfortunately, some patients initially respond to these treatments but then relapse, some patients' cancers do not respond at all, and the treatments can cause serious side effects. Scientists are working to understand the mechanisms underlying these challenges and to develop additional approaches for patients. Hundreds of clinical trials for new CAR T-cell therapies are ongoing, signaling the continued promise of this innovative new treatment for patients with cancer and HIV/AIDS.

Another area of NIH-supported research on personalized approaches to medical treatment has been to develop artificial pancreas technologies to automatically link individualized glucose monitoring and insulin delivery to improve the health and quality of life of people with type 1 diabetes (Figure 12). In the 1.6 million Americans estimated to have type 1 diabetes, the immune system destroys the pancreatic insulin-producing cells, leaving the body unable to absorb or use glucose. Significant progress toward artificial pancreas technologies—which consist of a continuous glucose monitor, an insulin pump, and a computer algorithm that, in some cases, can be run from the user's smartphone—has been made through extensive collaboration among NIH ICs, other federal agencies, private funders, academic investigators, and industry. In 2016, the FDA approved the first commercial hybrid artificial pancreas device[62] and in 2019, the FDA approved the first interoperable system[63] that could give patients the ability to choose the individual components that work best for them. Studies have shown that these technologies result in better control of blood glucose levels compared to standard treatment, potentially lowering the risk of diabetic complications.[64] NIH continues to support research to develop next-generation and novel devices that are smaller, easier to use, and available to all.

Figure 12. Artificial Pancreas

The Control-IQ artificial pancreas system was derived from research done at the Center for Diabetes Technology at the University of Virginia.

Catalyzing Cell Engineering, Bioengineering, and Regenerative Medicine

NIH is at the forefront of remarkable technological advances, such as innovations in cell engineering, bioengineering, and regenerative medicine. These advances are not only accelerating research but also creating the possibility of new treatments that previous generations of clinicians could only imagine. For example, scientists supported by the NIH BRAIN Initiative®[65] have pioneered a new technology that converts brain signals into audible speech—a potentially life-altering breakthrough for individuals who are unable to speak due to a stroke, injury, or other neurological condition. Next, researchers will design a clinical trial involving paralyzed, speech-impaired participants to determine how to best gather brain signal data, which can then be used to refine the previously trained computer algorithm.

Biotechnology is bringing us closer to a cure for AMD, a leading cause of visual impairment among older Americans. By 2050, the estimated number of people with AMD is expected to more than double from 2 million to 5 million.[66] The discovery of induced pluripotent stem cells (iPSCs)—adult cells that have been genetically reprogrammed to a developmental stage such that they can be turned into any cell type in the body—opened the door for transformative regenerative medicine therapies. Researchers at NIH were able to derive iPSCs from participants with advanced AMD and convert them into healthy retinal tissue. The newly developed tissue replaced damaged tissue and prevented blindness in animal models.[67] NIH received FDA approval to begin the first-ever clinical trial using replacement tissue derived from iPSCs in humans.[68]

Therapeutic development for many human diseases and conditions could become faster and more accurate due to the expanding use of tissue chips, or "organs-on-chips." These devices consist of 3-D platforms that support living human tissues or cells to model the structure and function of human organs, such as the lung, liver, and heart. Working closely with the pharmaceutical industry and FDA, the Tissue Chip for Drug Screening program[69] supports research using tissue chips to test new drugs and predict whether they will be safe and effective in humans. In collaboration with the International Space Station National Laboratory (ISS-NL) and the National Aeronautics and Space Administration (NASA), NIH is funding nine tissue chip projects in which different types of tissues are being sent to the ISS-NL to determine how human tissues behave in space when

exposed to reduced gravity,[70] which models aging in an accelerated manner (Figure 13). Researchers are also developing interconnected tissue chips that could model the entire human body's response to candidate therapeutics and are being deployed to address emerging health challenges, such as the opioid crisis and COVID-19 pandemic. In addition, current efforts are focused on the use of tissue chips to inform the implementation of clinical trials.

Meeting Emerging Public Health Needs

A critical focus of the NIH mission is readiness to address new and emerging public health needs rapidly, comprehensively, and efficiently. From the emergence of HIV/AIDS in the 1980s to the more recent outbreaks of infectious diseases—such as Zika virus disease, EVD, and COVID-19—to conducting research during an unfolding disaster like the Deepwater Horizon oil spill, NIH has been at the forefront of the global research response. NIH's role in combatting emerging threats involves identifying and understanding the responsible pathogens and their effects on the body, treating affected patients in the NIH Clinical Center as part of research studies, and conducting and supporting clinical trials throughout the nation and around the world.

The NIH Clinical Center is specially equipped with high-level respiratory isolation capabilities to handle patients with highly infectious diseases. In addition, the staff includes infectious disease and critical care specialists who have received training in strict infection control practices to prevent the spread of potentially transmissible agents. The Special Clinical Studies Unit is used for cutting-edge investigational clinical studies and treatments, ranging from EVD to universal influenza vaccine studies to treating patients affected by the COVID-19 pandemic.[71]

NIH can also swiftly mobilize its flexible infrastructure and collaborative research partnerships to help advance new and promising treatments, even in areas of armed conflict and tenuous security. NIH and the Institute of Biomedical Research in the DRC conducted the Pamoja Tulinde Maisha (PALM) clinical trial, meaning "Together Save Lives," in Kiswahili. The preliminary results were so compelling that the trial was halted, and the results were promptly made public to help save lives and stem the latest EVD outbreak.[72] All EVD patients in the DRC treatment centers are now treated with one of two treatment options based on the PALM trial results. Through this collaborative research conducted in a region of civil unrest during an ongoing outbreak, the U.S. and its partners have provided the world with two new effective treatments for an emerging disease. Additionally, this experience demonstrated the efficacy of promising therapeutics to treat EVD and serves as a potential guide for conducting future clinical trials in outbreak settings.

Figure 13. Tissue Chips in Space

An astronaut in a National Aeronautics and Space Administration spacesuit is shown with a kidney tissue chip in hand. When traveling in space, astronauts experience physiological changes normally associated with aging, such as bone loss, muscle deterioration, and altered immune systems. When the astronauts return to Earth, the changes often reverse. To better understand the relevance of the astronauts' experience to human health—both on the ground and in space—NIH partnered with the International Space Station U.S. National Laboratory to send tissue chips, a research technology that reflects the human body, into space.

Credit: NASA.

NIH's role in safeguarding the public health extends beyond infectious disease. For example, at this writing, opioid misuse and addiction continues to be a rapidly evolving U.S. public health crisis. Although more than 50 million Americans suffer from chronic pain, safe non-opioid options for pain management are unavailable.[73] In 2018, more than 46,000 Americans died of opioid overdose, making it one of the most common causes of non-disease-related deaths for adolescents and young adults.[74] More than 2 million Americans live with an opioid use disorder. To address this national crisis, NIH launched the Helping to End Addiction Long-term℠ (HEAL) Initiative,[75] an aggressive, NIH-wide effort to provide scientific solutions and offer new hope for individuals, families, and communities affected by this devastating crisis (Figure 14).

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Figure 14. HEAL Initiative℠

The NIH Helping to End Addiction Long-term℠ Initiative, or NIH HEAL Initiative℠, launched in April 2018, is an aggressive NIH-wide effort to provide scientific solutions to the national opioid overdose crisis, including improved treatment strategies for both pain and opioid use disorder. Notably, a series of highly focused studies has been launched to accelerate the development of new medications to treat all aspects of opioid use disorder, from new formulations of existing drugs to creating new therapies aimed at novel targets to novel devices for the treatment of substance use disorder and pain. Working across scientific disciplines and care settings, the NIH HEAL Initiative seeks to match the seriousness of the crisis and offers new hope for individuals, families, and communities affected by this devastating crisis. In partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA), in 2019 NIH launched the HEALing Communities Study to investigate how tools for preventing and treating opioid misuse and opioid use disorder are most effective at the local level.

Credit: NIH.

Partnering to Advance Treatments and Cures

Collaboration is essential to accelerating progress in developing effective prevention and treatment interventions, as well as ensuring that the benefits of research are available to all Americans. For example, the Partnership for Access to Clinical Trials is a collaborative effort that connects health care providers and their patients in the Washington, D.C., metropolitan area to NIH researchers conducting clinical trials at the NIH Clinical Center.[76] By serving as a bridge between research participants, their health care providers, and NIH researchers, this program serves as a successful model for increasing diversity in research participation, particularly among those who are underrepresented in clinical trials, and expanding access to the benefits of NIH research.

NIH facilitates collaboration with industry and federal partners to advance treatment science. In 2017, in collaboration with 12 leading biopharmaceutical companies and advocacy organizations, NIH launched the Partnership for Accelerating Cancer Therapies,[77] a 5-year public–private research collaboration, as part of Cancer Moonshot℠. The initial focus of the partnership is the development, validation, and standardization of biomarkers to better predict response to immunotherapy—a type of biological therapy that turns on or off the immune system to help the body fight cancer, infection, and other diseases. Immunotherapies have resulted in dramatic clinical benefit in certain types of cancer; however, existing immunotherapies do not work for all patients and are associated with substantial toxicity in some individuals.[78] A better understanding of why immunotherapies work in some patients and not others is needed to help target this treatment to the people most likely to benefit.

NIH is also transforming treatment of sickle cell disease (SCD) through collaborations (Figure 15). SCD is a group of inherited disorders characterized by the buildup of an abnormal protein in red blood cells. It can cause pain, fatigue, and damage to organs throughout the body. People of African ancestry have the highest prevalence of SCD; it is estimated that the disease affects up to 100,000 Americans.[79] Although treatments are available to relieve symptoms and extend lifespan, a bone marrow transplant is currently the only cure for SCD.[80] Unfortunately, a transplant is not feasible for most patients, because it requires bone marrow from an immune-matched sibling.

In 2016, NIH established the Sickle Cell Disease Implementation Consortium (SCDIC), the first

Figure 15. Sickle Cell Disease

In sickle cell disease, red blood cells make an abnormal protein that causes them to take on a sickle shape. These cells are inflexible and can stick to blood vessel walls, interrupting blood flow.

Credit: Janice Haney Carr and the CDC Public Health Image Library.

research program to use implementation science—the scientific study of how best to ensure the uptake of evidence-based practice—to identify and address barriers to quality care in SCD.[81] The SCDIC has created a registry of more than 2,400 patients. In 2018, NIH established the Cure Sickle Cell Initiative, an innovative collaboration among researchers in academia and industry, clinicians, patients, and advocates to identify and support the most promising genetic therapies for SCD.[82] Their goal is to bring new therapies to the point of FDA approval within the next 5–10 years.

NIH facilitates collaboration on complex scientific questions requiring the intersection of disciplines, methodologies, and knowledge by supporting a variety of funding mechanisms that are focused on collaborative or team-based work. Such opportunities for investigator-initiated research extend from serving as co-primary investigators on a grant award to participating in highly complex networks of investigators and institutions charged with advancing science in new directions. NIH looks forward to reaping the scientific benefits of continuing and expanding its partnerships in the next 5 years.

OBJECTIVE 2 Developing, Maintaining, and Renewing Scientific Research Capacity

NIH not only funds innovative biomedical and behavioral research but also pursues its mission by ensuring that the biomedical research workforce is well trained and diverse and conducts its work within an infrastructure that enables groundbreaking results at a rapid pace. Over the next 5 years, NIH is poised to enhance its support of research capacity to maximize the potential of the research that the agency sustains.

Enhancing the Biomedical and Behavioral Research Workforce

NIH recognizes that its mission will be met only through the continued efforts of a talented and dedicated biomedical research workforce. The strength of the NIH workforce depends on its sustainability and diversity (Figure 16), which NIH supports through both intramural and extramural focused training programs.

Sustainability is achieved by maintaining an appropriate balance of researchers at different career stages, ensuring that investigators early in their careers are given every opportunity to excel, even in times of limited funding. Intense competition for funding can pose a challenge for researchers trying to embark upon and sustain independent research careers. NIH's Next Generation Researchers Initiative (NGRI) aims to enhance opportunities for early-stage researchers by prioritizing funding of independent research applications for investigators who are within 10 years of completing postgraduate clinical training or their highest advanced research degree.[83] Through this initiative, NIH has more than doubled the number of early-stage researchers supported—from less than 600 in 2013 to 1,316 in 2019. Moving forward, NIH will continue to explore novel approaches to expand pathways for funding early-stage researchers and assess how NGRI policies affect women and individuals from groups that are underrepresented in biomedical and behavioral sciences.

To encourage early-stage researchers to explore new research avenues, NIH recently created the Stephen

Figure 16. Minority Women in Science

Alma Levant Hayden was one of the first minority women scientists in the federal government and worked at NIH as a biochemist. Photo taken around 1952.

Credit: NIH.

Ira Katz Award, in memory of the longtime director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. This award is designed to support earlystage researchers who propose innovative and unique ideas that represent a significant change in research direction from their past research or training experience.

Ground-breaking, impactful biomedical and behavioral research depends upon a diverse workforce, composed of people trained in multiple disciplines and from different backgrounds, who can provide a richness of perspectives necessary to inspire new ideas. Recognizing the need to advance talent in muchneeded fields of study, NIH supports training programs in a wide variety of areas, such as bioinformatics, scientific rigor and reproducibility, and data science. To illustrate, NIH supports 16 University-based Biomedical Informatics and Data Science Training Programs,[84] including more than 200 Ph.D.- and postdoctoral-level researchers. Notably, NIH also partners with high schools, minority-serving institutions, and others to support bioinformatics training.

Given the role that interdisciplinary approaches and team science play in fostering innovation, NIH has developed a number of initiatives to encourage collaborative research. One such example is NIH's Building Interdisciplinary Research Careers in Women's Health (BIRCWH), which connects junior and senior faculty with shared interests in interdisciplinary research on women's health.[85] Since 2000, BIRCWH has helped more than 700 junior faculty pursue their career goals, thereby expanding the pipeline of women's health researchers and benefiting the health of women.

NIH supports numerous programs designed to foster research environments that encourage participation from a full and diverse range of talent. NIH's Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program[86] facilitates the transition of promising postdoctoral researchers from diverse backgrounds, including those from underrepresented groups, to academic faculty positions at institutions throughout the country. The Native American Research Internship (NARI) program supports diverse student researchers, including American Indian and Alaskan Native students, from across the country in paid summer research internships. NARI researchers benefit from cultural and professional mentorship from American Indian or Alaskan Native elders, community organizations, and renowned faculty scientists.

Reflective of the high priority that NIH places on workforce diversity, the NIH Common Fund manages several training programs targeted on diversity. Launched in 2014, the Enhancing the Diversity of the NIHFunded Workforce Program[87] (also called the Diversity Program Consortium or DPC) encourages the inclusion of talent across the career span. Through integrated initiatives, DPC has supported thousands of trainees in biomedical and behavioral research careers by providing funding for institutional infrastructure, student support, and research mentoring. Within 4 years of launch, 1,116 students were appointed to research-training positions through DPC's Building Infrastructure Leading to Diversity (BUILD) program, with 68 percent of BUILD students from underrepresented groups.[88] Moreover, half of DPC member institutions (59 of 113) are either historically Black colleges and universities or institutions with a track record of training Hispanic or Latinx students. BUILD funding enables supported scientists to pursue research focused on understanding health disparities within and across underrepresented groups.

Plans are in place to launch the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) initiative.[89,90] Modeled on the NIH's Distinguished Scholars Program,[91] FIRST aims to transform culture at NIH-funded institutions through the recruitment of faculty cohorts who have a demonstrated commitment to diversity and inclusion. As it enters Phase II of its 10-year program, the DPC will continue to closely monitor the impact of these programs on the careers of individuals from backgrounds underrepresented in NIH-funded research.

NIH recognizes that women scientists often face institutional and environmental barriers that restrict their potential to advance their careers. The NIH Working Group on Women in Biomedical Careers aims to identify and remove barriers to the entry, recruitment, retention, and career development of women biomedical and behavioral scientists.[92] The working group contributed to such recommendations as extended periods for the consideration of tenure and parental leave, a grant program for research on causal factors and interventions that affect the careers of women in science and engineering, and workshops on mentoring women and best practices for women's career success. The Women of Color Committee within the

working group ensures that the unique career barriers faced by women of color are addressed.

Public health needs extend far beyond geographical borders. For example, deadly infectious diseases, such as EVD and COVID-19, can spread rapidly across international borders and continents. Recognizing that scientific research capacity is not equally distributed across the globe, potentially hampering the ability to combat such challenges, NIH develops international training programs. One such program, the Global Infectious Disease Research Training Program, builds infectious disease expertise and research capacity across the world and has prepared more than 1,200 researchers to conduct independent and locally relevant infectious disease research in their home countries.[93] The program connects U.S. institutions with institutions in low- and middle-income countries to provide degree programs, trainings, workshops, and mentoring on topics related to infectious diseases.

The COVID-19 pandemic has also shown the need for local epidemiological modeling capability to provide actionable information for policy makers to make public health decisions during outbreaks. NIH builds capacity for in-country analysis of COVID-19 in low- and middle-income countries by training modelers to track and analyze the progress of the pandemic. These activities include longstanding NIH partners who have well-established epidemiological and surveillance sites in Africa, South America, and South Asia, but lack analytical capacity.

Supporting Research Resources and Infrastructure

For the biomedical research workforce to succeed in moving discovery forward, it requires a scientific infrastructure that is expansive, durable, and capable of quickly integrating state-of-the-art resources that are available to all. To achieve this goal, NIH develops a number of programs and policies designed to provide the biomedical research workforce with stability and flexibility, broad access to innovations in tools and technologies, materials, and knowledge repositories necessary for the design of impactful research programs (Figure 17).

NIH's support of modern technology platforms and high-performance computing capabilities enables innovation in scientific research in several areas, particularly genomics, computational chemistry, and cryo-electron microscopy imaging. Cryo-electron microscopy is a cutting-edge technology that enables researchers to determine the structures of biological molecules to identify therapeutic targets for vaccines and drugs. NIH Common Fund's Transformative High Resolution Cryo-Electron Microscopy program[94] aims to broaden access to cryo-electron microscopy through the support of national service centers, improvement of technology, and training.

NIH is also investing in the data infrastructure necessary to accommodate rapid advances in biomedical and behavioral research. Research progress has produced an explosion of human health data that exceeds current abilities to capture and interpret them (Figure 18). To promote data sharing in high-priority research areas, NIH creates a number of different data repositories. For example, NIH has built a data repository to maximize publication availability and data sharing for NIH HEAL Initiative[SM] research projects.[95] This effort promotes dissemination of new knowledge, enhances reproducibility, and will accelerate the ability of researchers to build upon research to make new discoveries. In addition, the Data and Biospecimen Hub (DASH) is a centralized resource that allows researchers to share and access deidentified data, and for many studies, linked biospecimens are available to researchers.[96]

Figure 17. Zebrafish Facility

At the largest zebrafish facility on NIH's campus, Kevin Bishop, NIH Zebrafish Core staff member, holds up a tank of zebrafish to observe their behavior and physiology. Using molecular techniques, researchers alter the zebrafish's genome to mimic what is seen in human patients in the clinic.

Credit: Ernesto del Aguila III, NHGRI, NIH.

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Figure 18. Modern Data Environments to Accelerate Research

Rapid advances in data generation and computing power provide extraordinary potential for accelerating biomedical research. However, researchers face technical hurdles to accessing, sharing, and analyzing within and across large biomedical datasets. NIH is tackling this challenge through multiple initiatives to build modern technology platforms, collaborative workspaces, tools, and applications necessary for researchers to securely find, access, share, store, and analyze data across diverse datasets. Two examples are the Genomic Data Science Analysis, Visualization, and Informatics Lab-space and the Cancer Research Data Commons. These platforms enable researchers to efficiently combine and analyze diverse data types, which can lead to new discoveries in disease prevention, diagnosis, and treatment. Several programs seek to provide researchers with state-of-the-art, high-performance computing, such as the Biowulf cluster, which is the world's most powerful supercomputer completely dedicated to advancing biomedical and behavioral research.

Credit: Ernesto del Aguila III, NHGRI, NIH.

Much of NIH's efforts in resource building focuses on providing researchers with the underlying evidence needed to design impactful research programs. These efforts include the development of resources for understanding public health needs of the general population and specific populations, resources that will assist in providing access to patient populations, and resources for better understanding the factors affecting such health conditions as Alzheimer's disease and related dementias (Figure 19).

A widely available tool in which NIH invests to help guide prevention and treatment efforts is the Global Burden of Disease (GBD) enterprise.[97] GBD is the world's largest scientific effort to systematically quantify health loss from all diseases, injuries, and risk factors by age, sex, and geographic location over time. NIH and GBD collaborated to improve the way that disease causes and risk factors are identified. As a result of this collaboration, NIH and the research community can identify and track the causes and risk factors of premature death and disability in the U.S. over time (both historically and projecting up to 25 years in the future). Because premature death is often preventable, the availability of these data not only improves understanding of the burden of disease and key health outcomes in the U.S., but also enhances the ability to focus on the most pressing health challenges facing the nation.

The ability to monitor cancer in the U.S. is an important step toward determining how best to prevent and treat cancer in specific, disproportionately affected populations. The NIH Surveillance, Epidemiology, and End Results (SEER)[98] Program provides information on cancer statistics based on race, gender, and geography to guide efforts to reduce the cancer burden among the U.S. population. SEER currently reflects 35 percent of the U.S. population, and NIH

Figure 19. Alzheimer's Disease Research Infrastructure

More than 5.8 million Americans age 65 and older are living with Alzheimer's disease (AD), the most common form of dementia. Many others younger than age 65 have developed the less common early-onset form of AD. Still more are affected by AD-related dementias (ADRDs). Although the underlying pathology may differ among these conditions, their ultimate outcome is the same: the inexorable, relentless loss of memory, thought, and function. At present, no intervention has been reliably proven to prevent, slow, or reverse the effects of AD/ADRD. Under the auspices of the National Plan to Address Alzheimer's and Related Dementias, NIH develops and supports a robust infrastructure for discovery that supports activity across the full spectrum of AD/ADRD research, including, but not limited to, the Dominantly Inherited Alzheimer's Network, an international consortium of researchers who are working with individuals from families with a rare form of the disease to identify the sequence of brain changes before symptoms appear; the NIH Blueprint Neurotherapeutics Network, NIH's preclinical/early clinical drug development program that provides support for drug discovery and development; and the Alzheimer's Disease Education and Referral Center, NIH's primary source for consumer information on AD/ADRD research and care.

will expand the program to cover 50 percent of the U.S. population.

The medical advances and new technologies that have allowed Americans to live longer and healthier lives have not helped everyone equally. To build capacity at institutions with a historical and current commitment to educating underrepresented students and providing health care in underserved communities, NIH created the Research Centers in Minority Institutions (RCMI) Program.[99] The goals of RCMIs are to enhance institutional research capacity, enable investigators to become more successful in obtaining competitive funding, foster environments conducive to career enhancement, promote research on minority health and health disparities, and establish sustainable relationships with community-based organizations.[100]

NIH is also working to promote health equity in rural populations. NIH's Clinical and Translational Science Awards (CTSA) Program[101,102,103] is engaging with patients, community members, and nonprofit organizations to develop and disseminate best practices for patient-focused research in rural health.[104] Project areas include improving access to clinical trials for rural communities, harnessing technology to deliver effective care, and enhancing rural community outreach. The CTSA Program is also partnering with other NIH ICs and federal agencies to support rural health.

To further support rural communities, NIH is harnessing the Institutional Development Award (IDeA) Program, which aims to broaden the geographic distribution of NIH funding and to build research capacity in states that historically have had low levels of NIH funding. NIH is building on the research capacity within IDeA states to help address the medical needs of children living in rural and underserved areas. Similarly, the Environmental influences on Child Health Outcomes (ECHO) Program also leverages IDeA to expand pediatric research capacity in the IDeA States Pediatric Clinical Trials Network.[105] Beginning in 2018, IDeA also collaborated with NIH's Shared Instrumentation Grant (SIG) Programs to improve access to modern technologies for researchers in underresourced institutions in IDeA-eligible states. SIG supports the acquisition of modern scientific instruments that must be used on a shared basis.[106]

Many NIH Common Fund projects focus on developing resources that can be useful for research communities focused on a particular topic. The NIH Common Fund Molecular Transducers of Physical Activity Consortium (MoTrPAC)[107,108] is building a map of the molecular responses to exercise, both immediate and over the long term. Data are being made widely available to the entire research community so that investigators from anywhere can use this map to develop and test hypotheses about how exercise improves health and ameliorates disease. The program is scheduled to run through 2023 and released its first dataset through the MoTrPAC Data Hub in 2019.

Another valuable resource for the research community includes improved understanding of the biological and behavioral mechanisms of symptoms, which can improve patient outcomes. The NIH Intramural Research Program launched the Symptom Science Center (SSC)[109] to address the need for a more comprehensive approach to understanding the complex mechanisms underlying symptoms. Increased knowledge in this area can help develop precision health interventions to treat patients more effectively. Furthermore, the SSC serves as a nexus for collaboration among investigators from multiple ICs and is committed to training scientists and clinicians in symptom science.

OBJECTIVE 3 Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

As a steward of public resources, NIH has a responsibility to uphold public trust and confidence in the agency. In addition to fostering innovative research, NIH must endeavor to ensure that all of its operations and the research it supports are conducted efficiently, responsibly, ethically, and with integrity. Over the next

5 years, NIH is committed to taking additional steps to maintain and strengthen the processes by which it governs the conduct of science.

Fostering a Culture of Good Scientific Stewardship

This *NIH-Wide Strategic Plan* positions the agency to meet its mission by pursuing scientific opportunities when they arise, responding to ongoing and emerging public health needs, and addressing rare diseases. NIH research efforts also align with and reflect HHS's priority goals.[110] The agency promotes policies and programs that foster and ensure a strong foundation and culture of good scientific stewardship. As critical research needs arise, NIH will respond by ensuring that the scientific community has flexibility to quickly adapt to and address urgent public health issues.

Setting Priorities

Scientific priority setting at NIH encourages input from a range of sources, including the research community; public forums; the Advisory Committee to the NIH Director; U.S. Congress; Administration objectives; and consultation with advocacy groups, professional societies, and research participants. The NIH Director provides overall leadership to the ICs and OD offices, especially on efforts involving several components of the agency. Strategic plans developed by individual ICs and OD offices, committees composed of representatives from multiple ICs, and interagency working groups describe a multitude of scientific priorities and themes of interest to the agency.[111]

NIH demonstrates effective stewardship by supporting the most meritorious biomedical and behavioral research possible. The NIH peer review process assesses research grant applications for overall scientific and technical merit and ensures that applications receive fair, independent, expert, and timely reviews.[112] Scientific review panels are strategically formed to include reviewers who possess both broad and specialized expertise and who can address stability and recent trends in the field. NIH makes efforts to ensure that review panels reflect diversity in career stage, geographic region, and demographic characteristics. NIH staff seek input from a variety of sources to identify reviewers for panels, including NIH program staff and advisory councils, as well as scientific literature, meetings, and professional organizations.

The relative merit of applications as determined through peer review, in conjunction with input on mission relevance from IC Advisory Councils, informs IC Directors as they make funding decisions that consider mission focus, portfolio balance, scientific opportunity, emerging and ongoing public health needs, and stakeholder priorities. Balancing research with training and infrastructure—as well as distribution across basic, translational, and clinical research—are key factors taken into consideration in maintaining a diverse portfolio. NIH also considers the vital role of rare diseases research, through which unique biological insights are possible. This research is less likely to be supported by private funders than research into more prevalent disorders.

To maintain a peer review process of the highest caliber, NIH has developed an ongoing systematic multimethod evaluation that will objectively assess most peer review study sections over a 5-year cycle.[113] The aims of the system are to keep study sections aligned with the current state of the science, confirm NIH is attracting applications that propose cuttingedge science, and ensure that study sections are functioning efficiently with a balanced workload. Additional programs, such as the Early Career Reviewer Program,[114] help NIH refresh and diversify its pool of reviewers, while also helping investigators improve their grant-writing skills, develop research evaluation capacity, and strengthen critique-writing skills.

NIH proactively pursues scientific opportunities through a variety of programs that promote innovative research concepts and exploration of scientific hypotheses that could steer science in new directions. Additionally, NIH encourages team science and cross-disciplinary collaboration to propel research progress. NIH will continue to look for additional ways to capitalize on the intersection of scientific fields to further scientific progress and improve human health.

Monitoring Expenditures and Scientific Progress

NIH requires regular reporting from grant and contract award recipients on research progress, spending, and findings. NIH staff review these reports to ensure proper stewardship of federal funds and that supported research is fulfilling all terms of the funding agreement.

Another aspect of NIH stewardship is to provide the public with transparent and easily accessible information about NIH research awards and allow interested individuals to monitor NIH's support of research. The *NIH Research Portfolio Online Reporting Tools Expenditures and Results (NIH RePORTER)*[115] tool, for example, provides public access to information on the grants, contracts, and intramural research that NIH supports. Additionally, the *NIH Data Book*[116] provides quick access to key annual statistics, such as application success rates, workforce and training trends, the peer review process, and small business awardees. NIH will continue enhancing these and other tools in the suite of *NIH RePORTER* tools[117] to better meet information and communication needs in the coming years.

Making Evidence-Informed Decisions

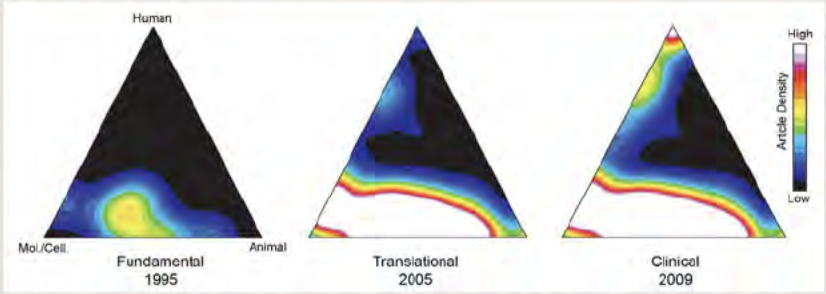
NIH is committed to enhancing scientific stewardship by optimizing approaches that generate evidence used to inform programmatic, operational, and policy decisions. To further these efforts, NIH has developed several tools, available to its staff and to the broader scientific community, that can identify and analyze current and emerging areas of research that will advance NIH's mission. For example, the *iCite*[118] suite of tools is a public resource that enables users to examine validated metrics regarding the impact of NIH-funded research articles (Figure 20). These tools, which are informed by the judgment of subject-matter experts, help users examine the NIH portfolio's productivity, balance, and priorities across the spectrum of research—from basic to clinical and across the diverse areas of biomedical and behavioral research.

NIH shares common interests with many agencies across the federal government and often coordinates with other science agencies to promote collaboration among researchers and manage research portfolios. NIH supports *Federal RePORTER*,[119] a collaborative effort among federal funders to provide a central database for certain grant information. In addition, NIH is partnering with the National Science Foundation and the General Services Administration to develop and implement computational tools to identify overlap between grant proposals across agencies in real-time, reducing the risk of unnecessarily duplicative research.[120] Collectively, these efforts promote transparency and enable efficiency through data-driven decision-making.

Assessing Programs, Processes, Outcomes, and Impact

The NIH *Report on Approaches to Assess the Value of Biomedical Research by NIH*[121] found that a better understanding of all aspects of NIH's work is key to increasing the efficiency and effectiveness of the agency. NIH uses a variety of approaches—including monitoring, performance measurement, analysis, and evaluation—to assess the progress and effectiveness of its programs, policies, and operations and to generate information for decision-making. To increase the use of these tools, NIH is enhancing the quality of administrative data, making it an increasingly strategic source of information that, when coupled with other tools, could improve the agency's

Figure 20. Predicting Translational Progress of Research



Credit: Hutchins BI, Davis MT, Meseroll RA, Santangelo GM. Predicting translational progress in biomedical research. PLOS Biol *2019;17(10):e3000416.* https://doi.org/10.1371/journal.pbio.3000416.

Fundamental research can take decades to translate into clinical outcomes. To capture the translational potential of publications, NIH researchers created a machine learning model that maps papers on a trilinear graph using three Medical Subject Heading (MeSH) terms: Human, Animal, and Molecular/Cellular. Almost all NIH-funded papers (> 96 percent) are assigned at least one of the MeSH terms and can be plotted somewhere on "the triangle of biomedicine." The graph pictured depicts the accumulation of fundamental, translational, and clinical research that led to cancer immunotherapy drugs like Opdivo (nivolumab). This visualization was generated using the *iCite* web tool developed by NIH.

effectiveness. Under HHS's guidance, NIH will engage in capacity- and evidence-building activities to support the Department's implementation of the *Foundations for Evidence-Based Policymaking Act of 2018*[122] and further develop its data-driven, results-oriented culture.

Communicating Results

NIH fosters scientific stewardship by ensuring that the products and processes of scientific research, such as research data and scientific publications, are available in accord with the FAIR principles that all research data should be findable, accessible, interoperable, and reusable (Figure 21). NIH communicates research findings to the public in numerous ways, including through press releases on recent scientific advances on the *NIH News & Events*[123] website, the *NIH Director's Blog*,[124] and the *Impact of NIH Research* pages,[125] which have examples illustrating the downstream impact of NIH research on public health and society. Additionally, NIH ICs and OD offices develop and disseminate a range of publicfriendly health- and disease-specific educational materials on a host of topics. NIH provides evidence-based and authoritative biomedical information in highly expeditious and proactive ways. This vital function is especially important during public health emergencies, such as infectious disease or foodborne illness outbreaks.

Figure 21. FAIR Principles

NIH is working to align the research that it supports with the FAIR principles (findable, accessible, reusable, interoperable) to ensure that the results of NIH investments can be leveraged by the entire research enterprise. NIH organizes its data science efforts around five themes: advancing data infrastructure to increase connectivity across systems and platforms; defining strategies to help researchers better store and share their data; adopting and adapting data science tools to enhance research; engaging with stakeholder communities and enabling citizen scientists to support the biomedical data enterprise; and increasing the capacity of computational and data science workers in biomedical research through new and existing workforce programs.

Credit: Office of Data Science Strategy, NIH.

Research results are also communicated through such NIH resources as *PubMed* and *ClinicalTrials.gov*. In 2020, NIH launched the new *PubMed*,[126,127] the most heavily used biomedical literature citation database in the world, which enables the communication and discovery of scientific literature around the world. NIH's *PubMed Central* (PMC)[128] provides public access to the full text of more than 6 million peer-reviewed research articles (Figure 22). PMC facilitates linking between articles and associated data; supports discovery of these data by aggregating data citations, data availability statements, and supplementary materials; and contains a subset of about 3 million articles available for bulk retrieval for text mining and other research purposes.

Reports from clinical studies are made available through *ClinicalTrials.gov*, the largest public clinical research registry and results database in the world. This NIH resource provides patients and their caregivers, health care providers, and researchers with information on more than 330,000 active and complete registered studies, including studies with summary results, many of which are not otherwise available through published literature. A multiyear effort is underway to modernize *ClinicalTrials.gov* to deliver an improved user experience on an updated platform that will accommodate growth and improve efficiency.

In response to the COVID-19 pandemic, NIH partnered with researchers and leaders from universities and industry to rapidly mobilize and create the *COVID-19 Open Research Dataset* (CORD-19)[129] of scholarly literature about COVID-19, SARS-CoV-2, and other coronaviruses. *CORD-19* provides immediate, machinereadable access to the full text of pre-print and peer-reviewed articles to assist researchers worldwide in finding answers to high-priority scientific questions related to the COVID-19 response. NIH also developed the COVID-19 portfolio tool[130] as a complement to *CORD-19*. This tool provides powerful search functionality and interactive

Figure 22. PubMed Central

As a free archive of full-text biomedical and life sciences journal literature, *PubMed Central* is an authoritative source of scholarly information that ensures the insights gained through biomedical discovery are made openly available to research and clinical care communities, as well as to the public at large.

Credit: National Library of Medicine, NIH.

visualizations to support cutting-edge analytics of the literature to identify gaps and opportunities in COVID-19-related research. In addition, to assist researchers working on the genomics of the novel coronavirus, the COVID-19 Genome Sequence Dataset on Registry of Open Data on Amazon Web Services[131] is a centralized sequence repository for strains of SARS-CoV-2.

Leveraging Partnerships

Expanding fundamental knowledge of biological systems and applying that knowledge to the advancement of health requires strategic partnerships with a range of organizations, including other federal agencies, international governments, the private sector, and the public. These partnerships bring enhanced coordination, critical expertise, pooled resources, and novel stakeholder connections to augment NIH efforts.

Federal Partnerships

NIH values collaboration with its federal partners and partners extensively with other federal agencies. Interagency collaborations address critical public health needs and facilitate coordination, communication, and resource-sharing. For instance, the Tobacco Regulatory Science Program (TRSP),[132] a partnership between NIH and FDA, funded research on youth tobacco use; toxins and nicotine concentration in e-cigarettes; and the Population Assessment of Tobacco and Health (PATH) Study, a longitudinal examination of tobacco product use.[133] Data from TRSP studies provide valuable evidence to inform government-wide policymaking. Research results from the Tobacco Centers of Regulatory Science, a centerpiece of TRSP, will provide further insight into who is using these products, what health outcomes result from product use, and how to implement interventions to target health outcomes.[134]

Another key federal collaboration is the Interagency Pain Research Coordinating Committee (IPRCC),[135] chaired by NIH with members from several agencies within HHS, including FDA, Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Department of Defense (DoD), and U.S. Department of Veterans Affairs (VA). IPRCC coordinates federal activities to enhance pain research efforts and promote collaboration across the government, with the ultimate goals of advancing the fundamental understanding of pain and improving pain-related treatment strategies. NIH also partners with DoD and VA on the NIH-DoD-VA Pain Management Collaboratory, which supports the development, implementation, and testing of cost-effective, large-scale, real-world research on nonpharmacologic approaches for pain management and related conditions in military and veteran health care delivery organizations.[136]

The *21st Century Cures Act* established the HHS Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) to advise the HHS Secretary regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women (Figure 23).[137] Led by NIH, other

Figure 23. Research for Pregnant and Lactating Women

The *21st Century Cures Act* established the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) to advise the Secretary of Health and Human Services regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women. PRGLAC was tasked with identifying these gaps and reporting its findings to the Secretary.

Credit: NICHD, NIH.

federal members include CDC, FDA, AHRQ, Health Resources and Services Administration (HRSA), VA, and HHS Office on Women's Health. Non-federal members include representatives from medical societies, nonprofit organizations, and industry. More than 6 million women are pregnant in the U.S. each year, many taking medications or dietary supplements. PRGLAC identified the lack of scientific evidence on the safety and efficacy of these compounds during pregnancy or breastfeeding as a substantial knowledge gap in maternal health.

Public-Private Partnerships

Public–private partnerships (PPPs) provide a mechanism to strategically accelerate advances and accomplish goals that NIH cannot readily achieve by acting alone. For example, to hasten the development of interventions for COVID-19, NIH is leading the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)[138] PPP (Figure 24). PPP activities focus on the shared goals and mandates of the partners and leverage knowledge, skills, resources, and services to achieve synergy. For example, NIH—together with FDA, biopharmaceutical companies, and nonprofit organizations—launched the Accelerating Medicines Partnership (AMP).[139] The goal of AMP is to increase the number of new diagnostics and therapies and reduce the time and cost of developing them. Four AMP initiatives are underway: AMPAlzheimer's Disease (AMP-AD), AMP-Parkinson's Disease (AMP-PD), AMP-Rheumatoid Arthritis/Lupus (AMP-RA/Lupus), and AMP-type 2 diabetes (AMP-T2D). After successfully meeting program milestones, AMP-AD and AMP-T2D are finalizing research plans for the next phase of the program. New AMP initiatives have been launched for schizophrenia[140] and are in development for gene therapy.

To capitalize on dramatic advances in genetics, NIH and the Bill and Melinda Gates Foundation have expanded their cooperation toward an audacious goal: to develop affordable, gene-based cures for SCD and HIV within a decade. The intention is for these cures to be made globally available, especially in lowresource settings where people are most affected by these conditions.

Figure 24. ACTIV: An Unprecedented Partnership for Unprecedented Times

In April 2020, NIH launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership to develop a coordinated research strategy for prioritizing and speeding the clinical evaluation of the most promising vaccines for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and treatments for coronavirus disease 2019 (COVID-19). Through ACTIV, NIH has partnered with more than 15 biopharmaceutical companies, as well as its sibling agencies and offices within the U.S. Department of Health and Human Services, other government agencies, the European Medicines Agency, and representatives from academia and philanthropic organizations. Through the ACTIV partnership, NIH is pursuing four fast-track focus areas most ripe for opportunity: (1) developing a collaborative, streamlined forum to standardize and share evaluation methods and testing of preclinical therapeutics and vaccines; (2) prioritizing and accelerating clinical testing of the most promising treatments for all stages of the disease; (3) leveraging clinical trial capacity and effectiveness; and (4) accelerating the evaluation of vaccine candidates to enable rapid authorization or approval.

Credit: NIH.

The NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative[141]—one of many NIH-wide efforts underway to implement the *NIH Strategic Plan for Data Science*—provides NIH and its funded researchers with cost-effective access to state-of-the-art cloud-based data storage and computational capabilities, tools, and expertise. Through STRIDES, NIH has established PPPs with commercial providers, such as Amazon Web Services and Google Cloud. NIH anticipates forming additional industry partnerships through STRIDES to broaden access to services and tools, including training and professional services for researchers on how to use the latest cloud tools and technologies. These partnerships will allow academic researchers and industry to come together to create a data ecosystem that maximizes the use of NIH-supported biomedical and behavioral research data for the greatest benefit to human health.

During the next 5 years, NIH will continue to expand partnership opportunities focused on increasing diagnostics and therapies for particular conditions, curing intractable diseases, and making the vast amount of data generated by biomedical research accessible to as many researchers as possible.

International Partnerships

As the world grows increasingly connected, NIH remains committed to developing and sustaining relationships with partners around the globe. Recent events, including the COVID-19 pandemic, have illuminated the importance of a coordinated approach to global health aligned with humanitarian and scientific values. Geographic boundaries do not prevent infectious disease spread, nor should they prevent the advancement of research on such diseases. For this reason, NIH collaborates internationally with foreign governments and organizations.

In collaboration with the Office of the U.S. Global AIDS Coordinator and Health Diplomacy, NIH supports the African Forum for Research and Education in Health (AFREhealth)[142,143] Program and the Health-professional Education Partnership Initiative,[144] both of which are designed to enhance the quality, quantity, retention, research engagement, and networking of an interprofessional health workforce across Africa. NIH also supports the Human Heredity and Health in Africa Consortium (H3Africa) via the NIH Common Fund.[145] This partnership includes the Wellcome Trust and the African Academy of Sciences and seeks to build African research capacity in the genomic sciences and contribute to improving understanding of health and disease in underrepresented and underserved populations.

NIH participates in the Global Alliance for Chronic Diseases (GACD),[146] a consortium of the world's largest public research funding agencies. GACD's mission is to reduce the burden of chronic noncommunicable diseases (NCDs) in low- and middle-income countries and in populations facing conditions of vulnerability in high-income countries, by building evidence to inform national and international NCD policies. NIH funds GACD research in the areas of cancer prevention, mental health, lung disease, type 2 diabetes, hypertension, and scaling-up evidence-based interventions.

In addition to working with international partners on disease, NIH also supports other types of international health initiatives. For example, the NIH Disaster Research Response (DR2) Program, which supports research to inform disaster and public health emergency preparedness, response, and recovery, serves as a compelling model for addressing crises. DR2 has partnered with Japan's National Institute for Environmental Studies and Health Canada to begin developing similar programs in those countries.[147] Early outcomes include translation of data collection tools to Japanese, using DR2 tools in response to Typhoon Hagibis, collaboration on DR2 workshops and training exercises, and international outreach.

Public Engagement

Public engagement is vital to NIH research. Patients, research participants, disease advocacy organizations, and local, state, and cultural communities have a leading role to play in the research enterprise. During study design, these groups can highlight important knowledge gaps impeding community-level programs, policies, and practices. During data collection and analysis, they advise researchers on the challenges of applying new knowledge in different local and cultural contexts.

As part of its commitment to public engagement, NIH will continue providing underrepresented groups with equal access to research in an ethical and responsible manner that protects privacy and respects cultural sensitivities. NIH facilitated a data sharing and use agreement between the Navajo Nation

and NIH grantees of the ECHO Program.[148] The agreement was created to advance the Navajo Birth Cohort Study while respecting Navajo Nation cultural beliefs, Tribal sovereignty, and community values.[149] It is the first Tribal data-sharing agreement for a large-scale database as part of a nationwide research consortium. This achievement lays the groundwork for discussion of similar agreements with other Tribal Nations considering participation in biomedical and behavioral research programs.

Public engagement is also key to NIH's maternal health efforts. The NIH Task Force on Maternal Mortality developed Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE), an NIH-wide research initiative. IMPROVE was informed by input from a variety of sources, including the public and NIH-convened meetings for scientists and clinicians to solicit recommendations on health disparities underlying maternal mortality, as well as gaps and opportunities for future research. IMPROVE will focus on women beginning in pregnancy and continuing up to 1 year postpartum and will include community-focused social and biobehavioral research, as well as research to accelerate discovery and advance technologies to reduce maternal health risks.

Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences

To foster confidence in NIH-funded research and results, NIH must ensure that both its operations and its supported research are conducted efficiently, responsibly, ethically, and with integrity. NIH is committed to taking steps to maintain and strengthen the processes by which it governs the conduct of science, continuing to be accountable for the public funds it invests in research.

Enhancing Reproducibility Through Rigorous and Transparent Research

Two cornerstones of scientific research are rigor in the design and conduct of experiments and the ability to reproduce research findings. The application of scientific rigor ensures robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results. When a result can be reproduced by multiple scientists working independently, it validates the original result and indicates readiness to progress to the next phase.

NIH has collaborated with scientific journal publishers to identify shared opportunities to enhance transparency, rigor, and reproducibility in published literature. NIH has also convened working groups and workshops focused on rigor, developed training modules for the research community on good experimental design, enhanced requirements for the content and review of grant applications, and developed specific funding opportunities aimed at improving rigor and reproducibility. Moving forward, NIH will continue working closely with researchers, publishers, and federal partners to develop and share recommendations and best practices. Along these lines, NIH has convened a working group of the Advisory Committee to the Director to explore ways to enhance reproducibility and rigor in laboratory animal research.[150]

Improving Stewardship of Clinical Trials

NIH invests more than $3 billion each year in clinical trials. NIH must ensure these trials investigate high-priority questions, do not needlessly duplicate previous trials, recruit and maintain sufficient participants, are completed in a timely manner, and are likely to advance knowledge and improve health. NIH has launched a series of efforts to enhance accountability and transparency in clinical research,[151] as well as address challenges and shortcomings in the design, efficiency, and timeliness of reporting clinical trial results. These efforts included dedicated funding opportunities, Good Clinical Practice training, a single Institutional Review Board for multisite research policy, and an optional template that guides investigators through the systematic development of a comprehensive clinical protocol and required registration and reporting of clinical trial results. In addition, by ensuring that summaries of results of NIH-supported clinical trials are widely and freely available, *ClinicalTrials.gov* promotes transparency and helps ensure that research findings are contributing to the advancement of public health.

Assuring Ethical and Equitable Conduct of Research Through Inclusion

More women and underrepresented and underserved groups are participating in clinical research than ever before, in large part thanks to NIH policy. NIH's goal is to ensure that these trends continue so that

the knowledge gained from research is applicable to everyone affected by the disease or condition under study (Figure 25). To this end, NIH has taken critical steps to ensure the scientifically appropriate enrollment of women and underrepresented and underserved groups in clinical research and is engaged in efforts to increase inclusion of children, older adults, pregnant and lactating women, and individuals with disabilities as appropriate. NIH requires researchers who propose research involving human subjects to include plans for how participants from these groups will be enrolled, unless there is a scientific or ethical justification for their exclusion. Once a grant is awarded, researchers must annually report deidentified individual-level demographic data so that NIH can continue to monitor inclusion.

Figure 25. Clinical Center Research

An NIH researcher examines a pediatric patient in the NIH Clinical Center.

Credit: Richard Clark, NIAMS, NIH.

NIH will continue its focus on challenges to recruiting and retaining underrepresented populations in clinical studies and will add data on the age at enrollment of participants to the Research, Condition, and Disease Classification (RCDC) *Inclusion Statistics Report*, which allows users to view trends over time. In addition, NIH will train researchers to include women, underrepresented and underserved populations, and individuals of all ages in studies as part of its efforts to increase the diversity of study populations.

Maintaining Transparency Through Data Access and Sharing

NIH is committed to making findings from the research that it funds accessible and available in a timely manner, while also providing safeguards for privacy, intellectual property, security, and data management. For instance, NIH-funded investigators are expected to make the results and accomplishments of their activities freely available within 12 months of publication. NIH also encourages investigators to share results prior to peer review, such as through preprints, to speed the dissemination of their findings and enhance the rigor of their work through informal peer review.

A robust culture of data sharing is critical to continued progress in science, maximizing NIH's investment in research, and assurance of the highest levels of transparency and rigor. To this end, NIH will continue to promote opportunities for data management and sharing while allowing flexibility for various data types, sharing platforms, and strategies. Additionally, NIH is implementing a policy requiring that all applications include data sharing and management plans that consider input from stakeholders.[152,153]

Fostering a Safe and Harassment-Free Work Environment

NIH has an imperative to transform the culture of science to prevent harassment (sexual, gender, and other) and mitigate its detrimental impacts, whether it is in the agency or anywhere NIH-funded activities are conducted. In 2019, NIH established the Advisory Committee to the NIH Director Working Group on Changing the Culture to End Sexual Harassment.[154] Following this group's recommendations, NIH is taking actions within the agency's authority to change the scientific workplace to make it safer and more welcoming (Figure 26). NIH issued several new policies, guidelines, and requirements on this topic and communicated them widely to make expectations clear to NIH-funded organizations and the workforce at NIH.[155]

NIH expects recipients of federal funds to have policies and practices in place that foster a safe and harassment-free environment.[156] For instance, NIH must be notified if a principal investigator or other key personnel named on an NIH grant award is unable to

Figure 26. NIH *Harassment Does Not Work Here* Campaign

An image stating "Harassment Doesn't Work Here" as part of NIH's campaign to create a safe and civil workplace wherever NIH-funded research is conducted.

Credit: NIH Civil Program.

fulfill their obligations to conduct research because they are under investigation or have been removed from the workplace because of sexual harassment concerns. NIH expects recipients requesting changes in investigator, key personnel, or recipient institution to mention whether these requests are related to concerns about the safety and/or work environment, including issues related to sexual harassment or bullying.[157] Internally, NIH has undergone a workplace climate and harassment survey to inform policy and practice and has expanded its human resources program to foster civility throughout the NIH community.[158]

NIH's efforts have led to increased scrutiny and awareness of harassment, centralized mechanisms for reporting harassment, and new anti-harassment policies. NIH will continue working with its partners and exploring policymaking options based on recommendations from the Advisory Committee to the NIH Director and findings from internal studies to change the scientific culture, prevent sexual harassment, and promote a civil, safe, and respectful workplace for everyone.

Managing Risks to the Research Enterprise

NIH is committed to proactively managing risks that may impede the NIH mission. Such risks have the potential to affect patient and laboratory safety, the peer review process, laboratory animal welfare, conflict of interest disclosures, closeout of grant awards, data security, and more. Understanding the need to identify and manage risks, NIH incorporated Enterprise Risk Management (ERM) capabilities into its strategic planning, performance management, and resource allocations (see Figure 27). Going forward, NIH is better prepared to respond to emerging risks that may undermine its research activities and are inconsistent with its research values and principles.

Figure 27. Managing Risks to the Research Enterprise

The NIH Risk Management Program provides NIH with a framework for systematically identifying and addressing risks that might adversely affect NIH's ability to fulfill its mission. Risk management is a continuous process that requires all NIH staff and researchers to proactively identify and mitigate risk as part of their daily jobs. Understanding the need to identify and manage risk, NIH has incorporated Enterprise Risk Management (ERM) capabilities into its strategic planning, performance management, and resource allocations. ERM is a strategic discipline that seeks to deliberately and proactively understand the full spectrum of risks, including opportunities across an entire organization, and integrates them into an enterprise-wide, strategically aligned, and interrelated risk portfolio view. By incorporating ERM, NIH can proactively address emerging threats and opportunities and deliver results to the public in a transparent and accountable manner, all in an effort to further support NIH's mission.

Credit: NIH Risk Management Program.

As a part of its commitment to a culture of health and safety for people conducting NIH-funded research, and to mitigating the effects of emergencies on the research enterprise, the NIH Extramural Response to Natural Disasters and Other Emergencies policy allows NIH to provide resources and assistance to those in the NIH community affected by public health emergencies.[159] Under such circumstances, NIH will provide administrative flexibilities and additional funding using a number of mechanisms to support the continuation of research, as demonstrated during the COVID-19 pandemic.[160]

NIH and the research community have a vested interest in mitigating any breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research, while continuing the tradition of scientific collaboration, including international collaboration. NIH recognizes the importance of these collaborations to advancing its mission. However, some researchers at NIH-funded institutions have taken advantage of these collaborations through failing to disclose contributions of resources from foreign organizations, diverting proprietary information to foreign governments, and sharing confidential information obtained from NIH peer review meetings or otherwise trying to influence the peer review process.

NIH works with other federal agencies to take strong actions in response to these breaches of integrity which appear to be, at least partly, instigated by foreign governments.[161] NIH has increased the visibility of this issue and reminds grant recipients to be transparent and disclose all affiliations, financial conflicts of interest, and other support (including from foreign entities) and contacts recipient institutions about any concerns.[162] NIH has also bolstered its internal processes and systems and increased awareness among its own staff.

Looking to the future, NIH will continue careful monitoring and extensive outreach with academia, professional societies, and federal partners to reinforce the importance of research security and integrity, as well as to hold people and institutions accountable for inappropriate actions.[163] NIH will continue to work closely with federal partners to protect the safety, integrity, and inclusivity of U.S. research and looks forward to continuing to work with institutions and researchers to strengthen values that underpin research integrity and protect the nation's biomedical innovations.[164]

Reducing Administrative Costs and Work Throughout the Grants Process

Reducing administrative burden increases the amount of time that investigators can spend on research and that administrators can spend supporting the research enterprise. NIH works to streamline grants policies and processes to reduce administrative work and costs. Recent changes include automating the issuance of certificates of confidentiality that protect participants in NIH-funded research, creating the Application Submission System & Interface for Submission Tracking (ASSIST) as an option for preparing and submitting applications, developing a tool that reduces the need to develop clinical trial protocol text de novo, simplifying the appendix and other material in grant applications to help during the review process, and reducing the need for multiple biographic profiles across different systems to help people find information and simplify reporting and analysis.[165] NIH will continue to work with stakeholders to further streamline the grant application process, while promoting rigor and fostering compliance.

Optimizing Operations

NIH seeks to continually optimize operations across an array of business, administrative, and scientific functions, as well as to improve its physical and technological infrastructures. Increasing coordination and engagement throughout the agency and managing risk while fostering innovation are critical to the stewardship of the nation's biomedical and behavioral research ecosystem. Over the next 5 years, NIH will implement strategies to excel as a federal science agency dedicated to protecting and improving public health.

NIH will continue implementing its *Optimize NIH* efforts, which were established as part of the *Reimagine HHS* effort to improve performance across the Department's divisions. Through the *Optimize NIH* initiative, the agency is focusing on administrative areas that could be made more efficient and effective if managed centrally, or better harmonized across ICs and OD offices. Using a combination of process mapping, surveys, and focus groups, the agency will carefully evaluate which approach or combination of approaches would yield the greatest improvements in each area. NIH's optimization efforts are guided in a data-driven and scientific manner, using teams led

by NIH experts in administrative operations with full engagement by employees.

Examples of functional areas that have already seen substantial improvement through *Optimize NIH* include management of federal advisory committees, employee ethics requirements, and *Freedom of Information Act (FOIA)* requests. NIH has adopted a unified system to standardize and streamline management of FOIA requests across the agency and has launched a public-facing portal, FOIAXpress, to improve the FOIA requestor experience. The launch of this portal increased information request processing speed by 83 percent, decreased the backlog by 11 percent, and offered solutions that can be leveraged across HHS. The lessons learned through the optimization of initial functional areas will inform NIH's approach to other business practice enhancements, such as information technology security, acquisitions, appointment of employees via a specialized hiring mechanism, travel management, and property management.

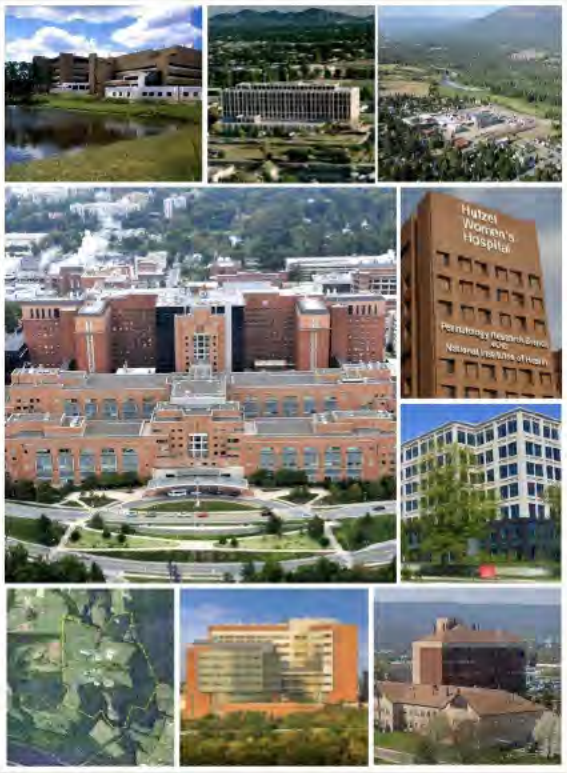
Optimize NIH will also continue to establish best practices for evaluating employee workload to improve the management of resources, inform hiring decisions, and reduce workload inequities. Workload harmonization across ICs and OD offices is already underway for scientific review, grants management, and program management, with additional areas identified for future improvement. NIH will also continue to harmonize and align each IC's strategic plan with a common template derived from the *NIH-Wide Strategic Plan*. Taken together, *Optimize NIH* projects will improve organizational effectiveness and performance and maximize the investment made by American taxpayers.

In alignment with the *Reimagine HHS* and *Optimize NIH* initiatives and in response to NIH community feedback, the NIH OD launched the OD Strategic Engagement Agenda to foster a unified and coordinated OD, which engages seamlessly with the ICs to advance the mission of the agency. This data- and participant-driven initiative will solicit and incorporate employee input through listening tours, working groups, and an online ideation campaign to improve communication and functionality within the OD through coordination and engagement with the ICs. By working toward these goals and improving on the use of OD operating principles of transparency, accountability, strategy, coordination, and decisionmaking, NIH will increase the efficiency and effectiveness of collaboration across NIH.

Meeting the goal of increased efficiency and effectiveness of operations across the agency requires the systematic assessment and management of risk in NIH's administrative and scientific programs, processes, and procedures. NIH is committed to integrating an ERM framework into its organizational culture to help prevent surprises, avoid operational failures, and allow quicker recovery when the unexpected happens. For example, NIH evaluated the extramural grant program using a fraud risk framework to identify vulnerabilities and develop mitigation strategies, including a staff fraud awareness and training program, to reduce the risk

Figure 28. NIH Campuses

Aerial views and photos of various building on NIH campuses showing a portfolio of biomedical research, administrative, and infrastructure-supporting facilities. From left to right and top to bottom: Research Triangle Park, North Carolina; Phoenix Epidemiology and Clinical Research Branch, Phoenix, Arizona; Rocky Mountain Laboratories, Hamilton, Montana; NIH Main Campus, Bethesda, Maryland; Pregnancy and Perinatology Branch, Detroit, Michigan; National Cancer Institute at Shady Grove, Rockville, Maryland; NIH Animal Center, Poolesville, Maryland; Bayview Campus, Baltimore, Maryland; and Frederick National Laboratory for Cancer Research, Frederick, Maryland.



Credit: Office of Research Facilities Development and Operations, NIH.

of fraud in the NIH extramural program and protect public funds. By conducting risk assessments and leveraging data collected within the ERM framework, NIH will improve information sharing and leadership decisionmaking and will prioritize corrective actions for identified risks. Incorporating ERM practices into daily operations also supports NIH in taking risks intelligently and prudently to achieve desired mission outcomes and enhances the agency's transparency and accountability to the public.

Underpinning NIH efforts to optimize its administrative and scientific operations are efforts to advance the agency's physical and technological infrastructures. For example, many of the agency's research and supporting facilities were constructed more than 50 years ago and require significant operating and maintenance costs, repairs, and upgrades to remain competitive in a global research environment. As resources become available, NIH will make strategic investments in building, expanding, and modernizing infrastructure on all its campuses.

It is critical that NIH provide, maintain, and operate its physical infrastructure—buildings and facilities capable of fulfilling and responding to the complex, collaborative, and changing nature of biomedical and behavioral science (Figure 28). The conduct of scientific discovery is enabled through safe and reliable facilities that can be adapted to support research on existing and emerging public health challenges, such as Alzheimer's disease and viral pandemics. NIH will closely link its strategic research goals to the availability, suitability, and capability of existing facilities and will plan, program, and budget for redeveloped and new facilities using planning and space utilization principles consistent with recognized business practices and the National Academies of Sciences, Engineering, and Medicine recommendations.[166] This integration of strategic research and infrastructure planning will enhance the oversight, prioritization, and delivery of facilities to meet the changing scientific needs over time.

CROSSCUTTING T

Many scientific challenges and opportunities are not unique to any one Objective in this Strategic Plan. To emphasize this, NIH has identified five key Crosscutting Themes that span all aspects of NIH's Strategy.

Improving Minority Health and Reducing Health Disparities

Underserved groups—including Black, Latinx, and Indigenous and Native American persons, Asian Americans and Pacific Islanders, and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; or persons otherwise adversely affected by persistent poverty or inequality—have distinct health needs and often experience disparities in health outcomes. NIH maintains that racial and ethnic minorities, rural residents, people with low incomes, SGM, and other populations experiencing health disparities should be included in all relevant research, such that there is sufficient representation of each population to conduct relevant analyses. Inclusivity in research generates more broadly applicable information and improves scientific understanding of the health and well-being of specific population groups.

To promote health equity, NIH remains committed to supporting a robust program of research examining how biological, behavioral, environmental, sociocultural, and other factors interact with and shape individuals' health trajectories across the lifespan. The science of minority health and health disparities is founded on the principle that the social construct of individual race and ethnicity and socioeconomic status influence behavior, biology, and health outcomes in many defined and undefined ways. These individual factors interact with structural social determinants that may promote cumulative adversity that leads to worsened health outcomes through biological mechanisms.

Racism and discrimination are increasingly recognized as contributing to poorer health outcomes for

racial and ethnic minorities and other disproportionately affected populations. There is also a growing societal recognition that racism and discrimination extend beyond the behavior of individuals and are embedded in social, institutional, organizational, and governmental structures, processes, procedures, and practices that limit opportunities and resources to segments of the population.[167] NIH understands that health research needs to routinely incorporate constructs and measurement of structural racism or discrimination across multiple domains and levels of influence if minority health is to be optimized, health equity achieved, and health disparities eliminated.[168]

Understanding why underrepresented groups experience specific health outcomes is at the core of minority health science. It is essential to identify contributing factors to minority health conditions independent of whether a health disparity exists or is identified. Minority health research is the scientific investigation of distinctive health characteristics and attributes of minority racial and/or ethnic groups that are usually underrepresented in biomedical research to understand health outcomes in these populations and develop interventions to reduce disparities in health outcomes The *NIH Minority Health and Health Disparities Strategic Plan*[169] sets the direction and goals for NIH research in this area. Several NIH ICs and OD offices have core missions to address the health of underserved and underrepresented populations and to ensure they are adequately included in all NIH research. In addition, NIH-wide strategic plans identify efforts specific to the needs of underrepresented populations to develop synergy and facilitate collaborations across NIH.[170,171,172]

Promoting the recruitment, retention, and advancement of scientists from underserved groups will also have a significant influence on workforce development and will provide opportunities for individual scientists to achieve their full potential, thereby improving research on minority health and reducing health disparities.

Women's Health

Enhancing Women's Health

Women's health is a wide-ranging topic that goes beyond reproductive health to address a broader spectrum of diseases and conditions experienced by women throughout their lifespan. To advance science for the health of women, the *Trans-NIH Strategic Plan for Women's Health Research*[173] established NIH priorities across the research continuum and emphasized the importance of interdisciplinary partnerships. The NIH policy on *Sex as a Biological Variable*,[174] along with the expanded *NIH Inclusion Policy*[175] that requires investigators to report Phase III clinical trial results by sex or gender, race, and ethnicity to *ClinicalTrials.gov*,[176] will build foundational knowledge, accelerate translational research, and ultimately enable women to receive evidence-based interventions specific to their needs.

Promoting the recruitment, retention, and advancement of women scientists will also have a significant influence on workforce development, as well as provide opportunities for individual scientists to achieve their full potential, thereby improving research on the health of women.

Public Health Challenges Across the Lifespan

Addressing Public Health Challenges Across the Lifespan

NIH supports biomedical and behavioral research applicable to the full spectrum of public health challenges and needs, such as acute and chronic diseases, persistent and emerging infectious diseases, cancers, substance use disorders, disordered eating, Alzheimer's disease and related dementias, the health impacts of environmental exposures, and many more.[177] NIH research must address the prevention, treatment, and management of public health challenges; meet new challenges with fundamental research; and be ready to mobilize cutting-edge science in emergent situations.

Many public health challenges affect people of various ages and populations differently. To promote health across the lifespan, NIH efforts include targeted studies of specific age groups; studies of diseases that are unique to, or more common in, certain age groups; longitudinal cohort studies that follow the health outcomes of groups of individuals over long periods of time (including across generations); and studies that examine how early exposures, adversity, and positive experiences affect later health outcomes. The critical issue of maternal mortality and morbidity in the U.S. is one example of a public health challenge that requires multifaceted approaches at different points in the lifespan. Risks include not only complications at the time of pregnancy, birth, and

postpartum, but also cumulative and intergenerational impacts and exposures.

In addition to these programmatic approaches, NIH policies set the expectation that all supported studies will be designed to include children and older adults unless there is a scientific or ethical reason to exclude them. This policy ensures that the scientific findings for a given disease or condition are applicable to all those affected.[178]

Collaborative Science

Promoting Collaborative Science

Complex public health challenges and scientific questions require collaborative, team-driven research involving experts working together across multiple scientific fields, resulting in innovations that exceed the capacity of a single laboratory or discipline. NIH promotes opportunities that bring together scientists and clinicians and recognizes patients and research participants as partners and collaborators to generate outcomes that address the public health challenges that communities face. NIH partners with a wide array of other federal agencies, and domestic and international organizations in the public and private sectors to leverage their respective expertise and translate NIH research findings into new therapies, technologies, and evidence-based practices for improving health. For example, efforts to accelerate COVID-19 diagnostics, therapeutic interventions, and vaccine development are being conducted alongside sister agencies within HHS and representatives from academic, nonprofit, and commercial organizations.[179]

Scientific progress also benefits from collaboration across NIH ICs and OD offices. These NIH collaborations occur at every level of NIH operation, resulting in innovative scientific programs that address a wide range of health conditions. For example, the Pediatric Research Consortium brings together staff from across NIH to discuss issues in pediatric research for a range of health conditions. NIH also cultivates strategic partnerships across HHS to strengthen the public health ecosystem. For example, NIH plays a key role in the Department-wide implementation and dissemination of the HHS Secretary's evidence-based initiative to combat opioid use disorder.

Data Science

Leveraging Data Science for Biomedical Discovery

An immense amount of data is generated throughout the research enterprise, from fundamental experiments using cells and model organisms to human clinical studies and community-level epidemiological research. The exponential growth of data has resulted from the development of advanced biomedical technologies and computational processing unavailable a decade ago, including advanced AI and virtual reality technologies. These transformative changes require innovative approaches and business practices to address opportunities and challenges in data science. Storing, managing, standardizing, analyzing, sharing, and disseminating vast amounts of data are therefore critical priorities for NIH.

The *NIH Strategic Plan for Data Science*[180] provides a roadmap for modernizing and integrating the NIHfunded biomedical data ecosystem, which comprises the universe of data infrastructure, resources, tools, and workforce. Combining existing strengths with new strategic partnerships, NIH works to ensure that data resources are guided by the FAIR principles (Figure 21).[181,182] Implementing the *NIH Strategic Plan for Data Science* will enhance the scientific community's ability to address new challenges, maximize the value of data generated, and accelerate discoveries that lead to better health outcomes. Woven into this plan is NIH's commitment to rapid, open sharing of data and greater harmonization of data science efforts across research domains, while respecting participant privacy, security of sensitive data, and Tribal sovereignty with respect to data.

A1404

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NIH National Institutes of Health

APRIL 2024

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

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

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.

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.

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).

A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271). Individuals with a Conditional Permanent Resident status may be supported on Kirschstein-NRSA training grants; however, as with all types of Permanent Resident status it is the recipient's responsibility to assure the individual remains eligible for NRSA support for the period of time of any appointment. Individuals with Asylum/Refugee status do not automatically hold a form of permanent residency status; they have the opportunity to apply for permanent residency status once they have been in the U.S. for a period of time. Therefore, individuals with Asylum/Refugee status may not be appointed to a Kirschstein-NRSA training grant until they have also secured permanent residency status. Individuals on temporary or student visas are not eligible for Kirschstein-NRSA support.

11.3.3 Application Requirements and Due Dates

11.3.3.1 Application

All applications for Kirschstein-NRSA institutional research training grants are submitted electronically through Grants.gov and use an application package that combines form components from the SF424 (R&R) application along with the PHS398 components. Application forms and instructions are provided as part of each NOFO. Applicants should pay particular attention to the special instructions for institutional research training grants found in the SF424(R&R) Application Guide.

11.3.3.2 Due Dates

Several NIH ICs receive training grant applications three times each year; however, many ICs use only one or two receipt dates. Information on IC-specific receipt dates is available in the *NIH Guide for Grants and Contracts* in the NIH-wide T32 and T35 NOFOs and NOFOs issued by the individual NIH ICs or by contacting the appropriate NIH IC program official. For a list of the standard receipt dates and review cycle, see the NIH Standard Due Dates website. (Also see http://researchtraining.nih.gov.)

Applicants are encouraged to contact the appropriate NIH staff before preparing and submitting an application. Applications requesting funding of $500,000 or more in direct costs for any year must generally include a cover letter identifying the NIH staff member within the specific NIH IC who has agreed to accept assignment of the application. NIH ICs, however, may opt to forgo this requirement for certain types of grants, such as training grants; applicants should consult the Notice of Funding Opportunity for specific instruction and/or contact the NIH IC if there are questions about the applicability of this policy.

11.3.3.3 Special Program Considerations

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Studies have shown that the length of the research training grant appointment of postdoctoral trainees with health-professional degrees strongly correlates to subsequent application for and success in receiving independent NIH research support. Therefore, Training PD/PIs should appoint only those individuals who are committed to a career in research and plan to remain on the training grant or in a non-Kirschstein-NRSA research experience for a minimum of 2 years in the aggregate. It also has been shown that transition to independent support is related to career success. Therefore, Training PD/PIs also should encourage and provide training in the skills necessary for postdoctoral trainees to apply for subsequent support through individual postdoctoral fellowships, mentored career development awards (K programs), or independent research project grants. When reviewing Kirschstein-NRSA institutional research training grant applications, peer reviewers will examine the training record to determine the average duration of training appointments for health-professional postdoctoral trainees and whether there is a history of transition to individual support mechanisms.

Programs located in clinical departments that focus on research training for individuals with the M.D. or other health-professional degrees should consider developing ties to basic science departments, or, if consistent with the goals of the program, modifying the program to include individuals with research doctorates. In these cases, applications should describe the basic science department's contribution to the research training experience and also indicate whether both health professional trainees and trainees with research doctorates will be included in the training program.

Training PD/PIs also must develop methods for ongoing evaluation of the quality and effectiveness of the training program. This should include plans to obtain feedback from current and former trainees to help identify weaknesses in the program and provide suggestions for program improvements as well as plans for assessing trainee's career development and progression, including publications, degree completion, and post-training positions. Evaluation results are to be included in competing continuation (renewal) applications and as part of the Final RPPR.

Within the framework of the program's longstanding commitment to excellence and projected need for investigators in particular areas of research, attention must be given to recruiting prospective trainees from diverse backgrounds, including racial or ethnic groups underrepresented in the biomedical, behavioral and clinical sciences, individuals with disabilities, and individuals from socially, culturally or economically disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research. Institutions are encouraged to identify candidates who will enhance diversity on a national or institutional basis. NIH's requirements for diversity recruitment and retention are described below.

11.3.3.4 Recruitment Plan to Enhance Diversity

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission.

Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research, and enhancing public trust.

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral and Social Sciences Research Enterprise

In spite of tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral and social sciences, such as:

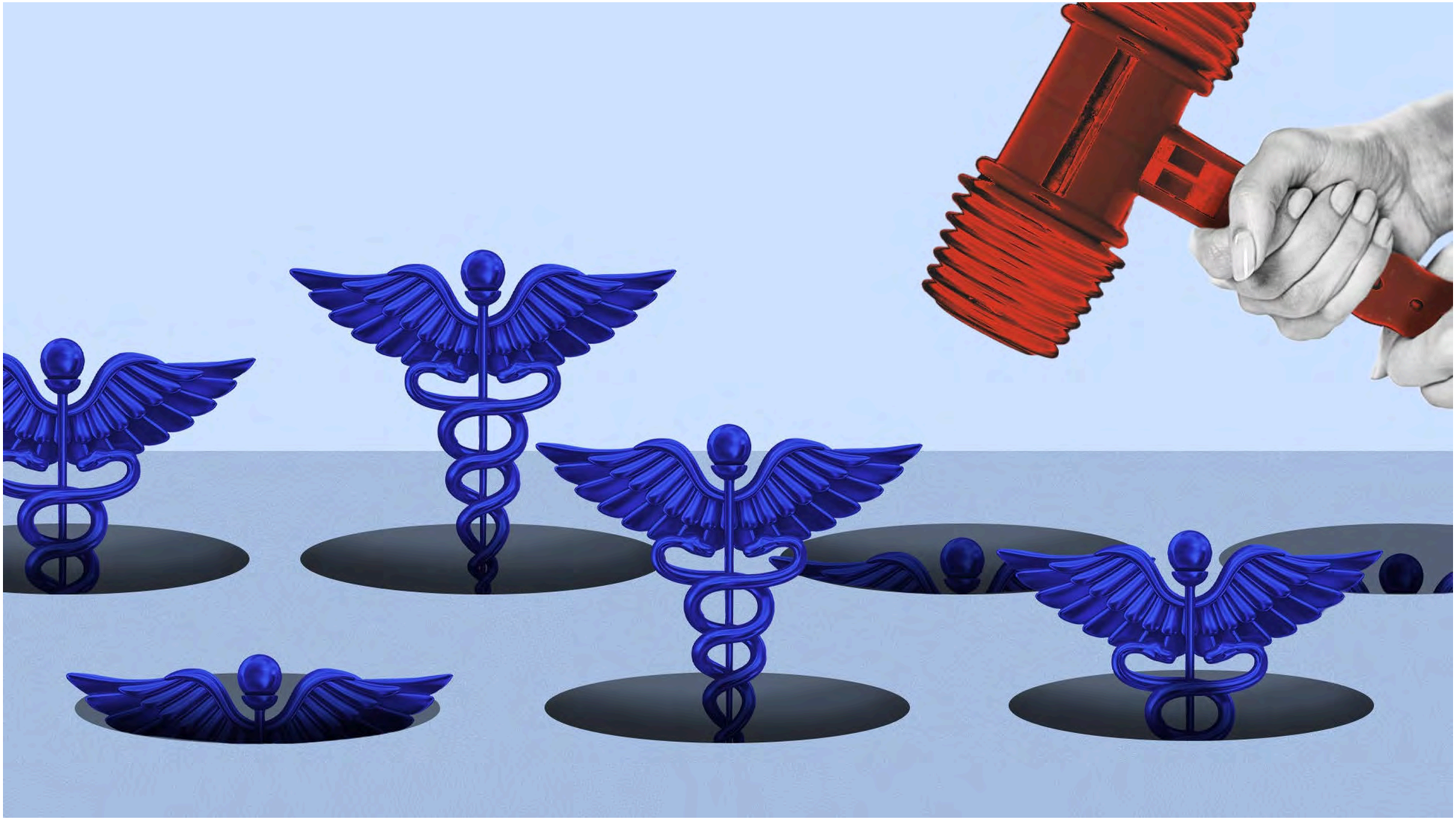
Read the detailed attack plans that Trump's advisers shared in the Signal group chat.

HEALTH

The NIH's Grant Terminations Are 'Utter and Complete Chaos'

The Trump administration is rapidly canceling hundreds of grants, in the most aggressive attack yet on American science.

By Katherine J. Wu



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MARCH 14, 2025

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Updated at 10:56 a.m. on March 14, 2025

Until the second Trump administration took over, the National Institutes of Health—the world's single largest public funder of biomedical research—was not in the business of canceling its grants. Of the more than 60,000 research awards the agency issues each year, it goes on to terminate, on average, maybe 20 of them, and usually only because of serious problems, such as flagrant misconduct, fraud, or an ethical breach that could harm study participants. "I have been involved with legitimate grant terminations," one former NIH official, who worked at the agency for many years, told me. "I can count them on the fingers of one hand."

Yet, in a few weeks, the administration has forced the agency to terminate so many of its active research grants—all seemingly on political grounds—that none of the dozen NIH officials I spoke with for this story could say for certain how many termination letters had gone out. Most thought that the number was now well above 100, and would likely continue to rapidly climb. This morning, in a meeting of grants-management staff, officials were told that approximately a thousand more grants could be targeted for termination, beginning today, one official told me. If the administration had not already, in a matter of weeks, exceeded the total number of cancellations the NIH has executed in the past *decade*, it will soon—perhaps within hours.

The NIH—an agency that has long prided itself on its mission of science funded by scientists—spends most of its $47 billion annual budget on driving biomedical innovation: developing new drugs and vaccines, containing epidemics, treating cancer, mitigating the harms of heart disease. But the growing scope of cancellations is revealing how willing Donald Trump's administration is to claw back those resources for political reasons. (All of the current and former NIH officials I spoke with for this story requested anonymity for fear of retaliation from the federal government; the NIH did not respond to a request for comment.)

This spate of terminations is the Trump administration's most aggressive attempt so far to forcibly reshape American science to match its agenda. At the same time, this might also be the most ham-fisted. Many officials told me that, as one succinctly put it, "they're just going in and picking random grants to terminate." Although the administration has said it doesn't want to fund science that touches on certain concepts—gender, DEI, vaccine hesitancy—the terminations so far have few discernible criteria, and don't operate by consistent protocols; in several cases, they end projects that are only tangentially related to the topics the administration wants to purge. If anything, the grant cancellations have become a game of whack-a-mole, in which political appointees take a mallet to any seemingly relevant research projects that pop into view—without regard to the damage they might do.

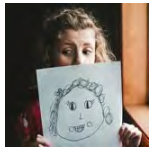
Notice of grant terminations has arrived from NIH officials, on NIH letterhead. But the decisions about which grants to cancel and why are

primarily being made outside the agency, with pressure coming from the Department of Health and Human Services, several NIH officials told me.

The first round of cancellations, which began on the evening of February 28, focused mainly on grants that included a DEI component or involved transgender participants; officials at the agency were also told to cut off funding to projects that allot money to China. Another round, which began on Monday evening, targets grants that mention vaccine hesitancy or uptake; that same night, the NIH posted on X that it would cut $250 million in grants from Columbia University, one of several institutions that the Trump administration's Department of Education is investigating for "antisemitic discrimination and harassment." Two officials told me they expect several more rounds of cancellations, and several said that, based on recent emails sent to staff, grants involving mRNA vaccines, as well as grants that send funds to work in South Africa, may be next. (HHS did not respond to a request for comment.)

The list of grants related to vaccine hesitancy that officials were told to cancel targets dozens of projects. Some—such as a study of vaccine uptake in Alaska Native communities—were perhaps obvious choices, because they so directly addressed

RECOMMENDED READING



Throw Your Children's Art Away

MARY TOWNSEND

vaccine attitudes. But the list also included studies that use vaccine hesitancy as just one of several variables to mathematically model disease transmission. And several researchers who have dedicated their career to studying vaccine behaviors have not yet heard that their grants have been affected. Alison Buttenheim, a behavioral scientist at Penn Nursing, has been watching colleagues' grants on vaccine uptake get canceled, but as far as she knows, her own NIH-funded work on vaccine hesitancy is still actively funded, though she expects that to change. "I figure it's only days until it's axed," she told me.

The Last Children of Down Syndrome

SARAH ZHANG

"It's unclear why some of us are getting them or not," Brittany Charlton, who directs the LGBTQ research center at Harvard's school of public health, told me. One of her colleagues, Nancy Krieger, told me that she'd received a termination letter for a study about measuring discrimination in clinical settings (including sexism and stigma about sexual orientation or transgender identity). But Charlton has yet to receive a letter for her own NIH-funded studies, which focus much more directly on LGBTQ populations.

One NIH official put it more bluntly: "It is such utter and complete chaos." In advance of the terminations, several officials told me, agency leadership solicited lists of grants that might, for instance, "promote gender ideology," or that involved certain types of vaccine-behavior research. NIH officials responded with curated lists of research projects, in several cases including only the bare-minimum number of grants with the most relevance. But many officials then received back spreadsheets populated with a subset of the grants from their own lists, along with several other grants that made only passing mention of the targeted topics. It was as if, one official told me, someone had performed a Ctrl+F search for certain terms, then copied and pasted the results. Multiple rounds of terminations in, officials at some NIH institutes are still unclear on how this new system of cancellations is supposed to work. Nearly two months after Trump's executive order on cutting DEI programming, for instance, "we still haven't gotten a definition of DEI," one official said.

Typically, each NIH grant is shepherded by a team of officials, including at least one program officer, who oversees its scientific components, and a grants-management officer, who handles the budget. When terminations are on the table, those officials are always looped in—usually so they can help determine how to remedy the situation. "Terminations are the *final* option," one NIH official told me.

But these recent directions to terminate arrived without warning or the usual steps of deliberation, and they instructed grants-management officers to issue letters by the end of the day they received them, two officials told me—leaving no time to push back, or even react. "There is zero protocol," one official told me. "It is just, *We are told, and it is done.*" In at least one case, an official told me, a program officer learned that their grantee's award had been terminated from the grantee.

The emailed directives also handed NIH officials prewritten justifications for termination. None cited misconduct, fraud, or even low likelihood for success. But the ones targeting research related to transgender people or DEI claimed that the projects in question were "antithetical to the scientific inquiry," "often unscientific," or ignoring "biological realities." The termination-letter templates also noted the NIH's obligation to carefully steward taxpayer dollars, accused the projects of failing to employ federal

resources to benefit the well-being of Americans, and cited new agency priorities as a reason for ending studies. Letters issued to several researchers studying vaccines, for instance, stated, "It is the policy of NIH not to prioritize research activities that focuses [*sic*] gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment." The terminations sent to scientists studying LGBTQ populations contained similar language, and in some cases said that their projects "provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness."

Those assertions, though, directly contradict the conclusions of NIH officials and the outside scientists who helped award those grants in the first place. No project can receive NIH funds without first being vetted by multiple panels of experts in the field, who judge each proposal based on criteria such as the lead scientist's track record, the rigor of the study's design, and the project's likelihood of addressing a pressing biomedical-research issue. And each proposal submitted to the NIH undergoes two layers of internal review, to

ensure that the project meets agency policies and is "aligned with the goals of the institute" potentially funding it, one official told me.

Several letter recipients told me that their grants had received perfect or near-perfect scores in early reviews; others told me that their results were well on their way to publication, proof of some return on the agency's investment. And all addressed important issues in public health: One, for instance, was studying how stress affects alcohol consumption; another, mpox among men who have sex with men; another, the factors that might influence the success of a future HIV vaccine.

The NIH, a federal agency directed by a political appointee, does sometimes shift its priorities for scientific or ideological reasons. For instance, some NIH institutes have over time gotten pickier about issuing awards to candidate-gene studies, in which researchers try to confirm whether a specific gene affects a biological trait, one official told me. And the first Trump administration placed restrictions on research that could be done using fetal tissue. Both of those shifts, officials said, meant that certain new proposals

weren't green-lighted. But in neither case was the agency forced to issue mass terminations of projects that had already been declared worthy of funds, officials told me.

The clearest example that the NIH officials I spoke with could recall of a grant being terminated at the behest of political leadership was also triggered by a Trump administration: During his first term, Trump pressured the agency to terminate a grant that had been issued to the nonprofit EcoHealth Alliance, which was partnering with the Wuhan Institute of Virology, in China. But even that cancellation was partly reversed. In general, "when an administration changes priorities, they change them going forward," one official said. "They don't reach back and terminate awards."

Grant cancellations are tantamount to instantaneous salary cuts for scientists, and can force them to halt studies, fire staff, and tell participants that their time and effort may have been wasted. Jace Flatt, a health and behavioral scientist at the University of Nevada at Las Vegas, has had two NIH grants

axed, for projects looking at dementia and memory loss in aging LGBTQ populations. If he loses a third NIH grant—as he expects to, he told me—"my lab is gone." Because the terminations arrived without warning, scientists also had no time to prepare: Sarah Nowak, a vaccine researcher at the University of Vermont, told me she found out that her grant investigating childhood vaccine hesitancy in Brazil was likely on the chopping block when she read an article on the vaccine-related grant cuts in *The Washington Post* on Monday. (Nowak received her letter the next day.)

Many studies, once terminated, would be difficult, if not outright impossible, to restart, Sean Arayasirikul, a medical sociologist at UC Irvine, told me. Medical interventions in clinical trials, for instance, can't simply be paused and picked back up; many studies also rely heavily on collecting data at small and regular intervals, so interruptions are equivalent to massive data holes. Plus, participants released from a study won't always be willing to come back, especially if they're from communities that medical research has neglected in the past and that already have little reason to place continued trust in

scientists. (Arayasirikul received a termination letter for their work investigating how stigma affects HIV preventive care for people of color who are also sexual and gender minorities.)

Terminating grants to match political priorities also creates a fundamental instability in the government's approach to scientific funding. If researchers can't count on grants to carry across administrations, their government-funded work will become a series of short-term sprints, making it harder for science to reliably progress. Biomedical breakthroughs—including, say, the generation and approval of new drugs, or clinical trials for chronically ill patients—typically take years, sometimes even decades. And for an administration that has premised itself on efficiency, a never-ending loop of funding bait and switch does not exactly make for minimizing waste. "This says, *At any point, we can just up and change our minds*," one NIH official told me. "That is not good stewardship of federal dollars."

Many of the administration's actions might well be illegal—especially its targeting of DEI, which a federal judge recently deemed a potential violation of the First Amendment. But NIH officials have been put "in an impossible position," one told me. Their choices are to either carry out the administration's wishes and risk defying court orders or resist the changes at the agency and directly disobey their supervisors, putting themselves "at risk of insubordination and therefore unemployment," the official said. Many have been choosing the first option, perhaps because the threat of losing their livelihood has felt so much nearer, and so much more tangible: They have now spent weeks watching colleagues resign, get fired, or be abruptly put on administrative leave. The environment at the agency has become suffocatingly toxic. "People are being screamed at, bullied, harassed," one official told me. Some that once protested have since relented—perhaps because they now know that the immediate future will bring only more of the same.

ABOUT THE AUTHOR

Katherine J. Wu

Follow

Katherine J. Wu is a staff writer at *The Atlantic*.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

STATE OF WASHINGTON, et al., Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States, et al., Defendants.) NO.2:25-cv-00244-LK

Washington, D.C.
Thursday, April 3, 2025

Deposition of MICHELLE G. BULLS, a witness herein, was called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to notice, the witness being first duly sworn by BESS A. AVERY, a Notary Public in and for the District of Columbia, taken at the offices of B&A Litigation Services, 1029 Vermont Avenue, N.W., Washington, D.C., commencing at 9:06 a.m., when were present on behalf of the respective parties:

2011. Did I get that right?

A 2012.

Q 2012. So since 2012, there's been one or two noncompliance terminations until about January 20th, 2025. Is that right?

A Yeah. And it's probably more than one, for sure, and less than a handful. So I don't recall, so I apologize, but I just know that that's not what we normally do. And, yes, the answer to the question is whether -- actually --

Q What were you going to say?

A No, I need you to repeat the question again, because I want to make sure I don't restate it incorrectly.

Q Sure. No, that's fair, that's fair.

My question was just between when you were appointed director in 2012 until January 20, 2025, there's been, I think you clarified, more than one but less than ten noncompliance terminations. I think that's what your testimony was.

A My testimony was it doesn't happen often, more than one and probably less than five.

Q More than one, less than five. Okay.

And since January 20, 2025, to the present date, how many noncompliance terminations have there

been?

A Zero.

Q Oh, okay. None at all. Were they all the bilateral terminations you were just talking about?

A We had some bilateral terminations between January, yes.

Q Okay.

A And I don't recall the number, but not any noncompliance.

Q So then the thread we were talking about with Dr. Kym Ahrens, it's been reinstated now, but when it was terminated, what kind of termination was that?

A A termination that was provided to me, to this -- yeah.

Q Okay. It was neither noncompliant nor was it bilateral?

A Correct.

Q Okay. It was a different kind of termination?

A Correct.

Q How many of that kind of termination was there between when you were appointed director of OPERA until January 20, 2025?

A Zero.

Q Zero. That never happened before?
A I'm sorry, let me restate. There was one termination that happened that way, but it was -- the grant was reinstated as well. That, yes.
Q Okay. Which one was that?
A That was one under the first Trump Administration for the Eco Health Alliance.
Q Okay. Do you know why that one was reinstated?
A No.
Q Okay. Okay. You just stated that this particular kind of termination, like for a Dr. Ahrens, was provided to you. Who provided it?
A Liza Bundesen, my supervisor.
Q Okay. And I think you said it was provided by someone in HHS, I forget her name, Rachel something?
A Rachel Riley.
Q Rachel Riley?
A Correct.
Q Okay. And just to clarify, Rachel Riley provided that list to Liza Bundesen, and that included the termination to Dr. Ahrens?
A Correct.
Q Okay.

basis of agency priorities, haven't they?

A Yes.

Q But you don't have agency priorities that are final?

A I have letters that I've been asked to send.

Q Okay.

MR. McGINTY: Can I mark this as Exhibit 4, please.

(Bulls Deposition Exhibit 4 was marked for identification.)

BY MR. McGINTY:

Q I'm passing to you what has been marked Exhibit 4, and do you recognize this document?

A Yes.

Q And what is it?

A A termination letter.

Q This is one of those letters that you've been asked to send that you were just talking about?

A Yes.

Q And you signed this letter, right?

A Yes.

Q Okay. And why did you send this letter?

A I was asked to send it.

Q Who asked you to send it?

A My supervisor.

Q Okay. And who is that?

A At the time, Liza Bundesen.

Q Okay. How did she ask you to send it?

A Via e-mail.

Q Did she tell you why she was asking you to send it?

A Yes.

Q Okay. And what did she say?

A That we were asked to terminate grants.

Q Did she tell you why you were asked to terminate grants?

A She did not.

Q Okay.

A Can I correct the statement?

The e-mail that I received from Liza Bundesen indicated that we needed to terminate the grants, and the language in the letters were provided so I didn't question, I just followed the directive.

Q Okay.

A She didn't say: Terminate the grant because of. She said: The list below. So I just wanted to be clear about that.

Q Okay. And did you provide this e-mail to

counsel?

A Yes.

Q Okay. And "the list is below," list of what?

A Awards to be terminated.

Q Okay. And is that the same list that you were talking about earlier that came from Rachel Riley?

A That was on the same e-mail, yes.

Q Okay. And Brad may have been copied on that e-mail?

A I don't know if Brad was on that e-mail string.

Q Okay.

A I can't recall.

Q Brad was on one of the e-mail strings?

A Correct.

Q Do you remember if it was Brad Smith?

A I know for sure Brad.

Q Okay. Definitely Brad. It might have been Brad Smith, it might have been Brad someone else?

A Yes.

Q Okay. And you said the language was provided. What do you mean by "the language was

provided"?

A The letter. There were template letters.

Q So the entirety of the letter language?

A Correct.

Q Okay. So take a look at the first paragraph here:

"Funding for Project Number," and then there's a number," is hereby terminated pursuant to the 2022 National Institutes of Health Grants Policy Statement," and C.F.R., a CFR section. "This letter constitutes a notice of termination."

You did not write that language?

A No.

Q You didn't write any word in this letter?

A Just the signature.

Q Okay. You wrote your name?

A Correct. I mean, I -- yes, I wrote my name and signed it.

Q Okay. And you don't know why this letter was sent?

A To terminate the grant.

Q Okay. But you don't know what agency priorities are intended to be served by terminating this grant?

A I didn't ask the question and I was not told, I sent the letter as it was.

Q Okay. Did Rachel Riley provide the templates that you used?

A Yes.

Q So it says here -- actually, can you read the fourth paragraph, the one that starts with, "This award no longer effectuates."

A "This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs."

Q Okay. And this was part of the template letter that Rachel Riley provided?

A Yes.

Q Are you aware of -- let me strike that.

Did NIH have any ability to alter this language in any way?

A Did we have the ability?

MS. ANDRAPALLIYAL: Objection, assumes facts not in evidence.

BY MR. McGINTY:

Q Was this edited in any way from the template letter that Rachel Riley provided?

A No.

Q Okay. It says, "Your project does not satisfy these criteria." Do you see that there?

A Yeah.

Q Are you aware of any assessment of Dr. Ahrens' grant in particular that was made to see if her grant satisfied the criteria?

A No.

Q Would you have been aware of such assessment if one had been made?

A I don't know.

Q Okay. Would you have been aware of such an assessment if one had been made by NIH?

A Yes.

Q And it says, "Research programs based on

gender identity are often unscientific with little identifiable return on investment, and do nothing to enhance the health of many Americans."

Did NIH do any assessment of this particular grant to see if it was unscientific?

A I don't know. The letter was provided and it was sent. I don't know what happened before that.

Q Well, did NIH do any assessment?

A I don't know.

Q You don't know if NIH did an assessment to see if Dr. Ahrens' grant was scientific or not?

A Are you talking about -- I don't understand your question, sorry.

Q Well, it says in this letter, and I understand you didn't write it, but you signed it, "Research programs based on gender identity are often unscientific." And that was the reason this particular grant was terminated.

Is that right?

A That's what the letter says.

Q That's what the letter says. So I'm trying to figure out whether or not there was any basis to think that Dr. Ahrens' grant was unscientific.

A I don't know.

Q Okay. And do you know if there was any assessment to see if it had an identifiable return on investment?

A No, I don't know.

Q Do you know if NIH did one?

A I don't know.

Q Okay. Would you have been aware if NIH did one?

A I'm not sure.

Q Okay. And it also says, "and do nothing to enhance the health of many Americans."

Do you know if NIH did any assessment to see if Dr. Ahrens' grant would enhance the health of many Americans?

A I don't know.

Q Okay. Was this the only template language that Rachel Riley provided?

MS. ANDRAPALLIYAL: Objection. To the extent that you're calling for draft language that wasn't finalized, that's privileged, and I instruct the witness not to answer.

BY MR. McGINTY:

Q I'll clarify.

Did Rachel Riley provide any other

template letters that were sent?

A Yes.

Q Okay. What were those template letters about?

A In that list, I don't recall.

Q How about any list for letters that had been sent?

A DEI activities, this language. I think one on China. I don't know. That's it that I can recall, and I'm sure I'm blanking right now.

Q So what you remember is the gender identity language, the DEI language, and the China language.

Was there language on vaccine hesitancy that was used?

A In that batch, no.

Q Any batch that's been sent?

A Yes.

Q And that was provided by Rachel Riley, too?

A Yes. Well, actually, that was provided by Dr. Memoli. I don't know if Rachel Riley provided that to him, I apologize.

Q Okay. So Dr. Memoli wrote the one on -- or provided you with the one on vaccine hesitancy?

Q And it says:
"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."
Do you see that?
A Yes.
Q This language was provided by Rachel Riley?
A Yes.
Q And then it says:
"DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to 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."

That language also was provided by Rachel Riley?

A Yes.

Q And, finally, the transgender language that we looked at before which was also provided by Rachel Riley?

A Yes.

Q And it was provided by her in the form of template letters to terminate grants?

A Yes.

MR. McGINTY: Mark this as Exhibit 6, please.

(Bulls Deposition Exhibit 6 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 6, and I'll represent to you that this was also published in the Nature journal, and I've printed it off of their website.

it doesn't include all of this detail that was provided in the termination letter. It just gives the title, the category.

Q So it says China, DEI, or transgender?

A Yes, and vaccine --

Q And vaccine?

A -- hesitancy.

Q Okay. When you get that list and you get the template letters, do you get a letter for each grant that you're going to terminate, or do you have to do some kind of, like, word merge?

MS. ANDRAPALLIYAL: Objection. The question is calling for provision of deliberative information which is privileged. I'm instructing the witness not to answer.

BY MR. McGINTY:

Q Okay. But it's your testimony that the reason that the grant is going to be terminated is provided to you. Is that right?

A That's right.

Q And you don't have any input into that?

A I don't.

Q Okay. And you're testifying that the template letter for each reason is provided to you. Is that right?

A Yes.

Q And you don't have any input into that either?

A I don't.

Q Okay. And how many of these lists have you gotten to terminate grants?

MS. ANDRAPALLIYAL: Objection. To the extent this information is deliberative and nonfinal, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q How many lists have you gotten for grants that have been terminated?

A More than five.

Q And how many grants have you terminated on the basis of these lists?

A Lots of grants. I don't know the number.

Q More than a hundred?

A More than a hundred.

Q More than a thousand?

A No.

Q Somewhere between a hundred and a thousand?

A Somewhere between five hundred and a thousand.

Q Somewhere between five hundred and a

thousand.

A Mm-hmm.

MR. McGINTY: This is Exhibit 7, I think we are on.

(Bulls Deposition Exhibit 7 was marked for identification.)

BY MR. McGINTY:

Q Do you recognize this document?

A Yes.

Q And you wrote this document, right?

A I wrote it with Dr. Lauer, yes.

Q Okay. And what is it?

A It's the supplemental -- it's the beginning of the guidance providing agency -- I mean ICs with guidance on how to unpause funding.

Q And it does say that there is a restriction. What's the restriction that it gives guidance about?

A On spending funding related to DEI activities on grants.

Q Was there a definition of DEI activities provided with this memo?

MS. ANDRAPALLIYAL: Objection. To the extent the information sought is deliberative and not final, I'm instructing the witness not to

answer.

BY MR. McGINTY:

Q How are ICs supposed to determine if something fell within DEI activities?

A They have scientific, the scientific background and they know their programs, so the Grants Management officials work with the program officials to identify DEI activities where it's not clear in the statute.

Q Are you aware of any statute that talks about that?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion and assumes facts not in evidence.

BY MR. McGINTY:

Q You can answer.

A The Minority Health Disparity Institute does have language about minority health and that kind of thing. So I don't know if it's -- I don't think it ties directly, but I think that is being used. And that's an assumption, that's not facts.

Q Okay. You said the Minority Health and Research Institute? Did I get that right?

A Minority Health Disparity.

Q Minority Health Disparity Institute.

What's the purpose of the Minority Health

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

STATE OF WASHINGTON, et al., Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States, et al., Defendants.) NO.2:25-cv-00244-LK

Washington, D.C.
Friday, April 4, 2025

Deposition of LIZA Q. BUNDESEN, a witness herein, was called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to notice, the witness being first duly sworn by BESS A. AVERY, a Notary Public in and for the District of Columbia, taken at the offices of B&A Litigation Services, 1029 Vermont Avenue, N.W., Washington, D.C., commencing at 9:06 a.m., when were present on behalf of the respective parties:

February 28th?

A Can you please clarify.

Q How did you first learn that grants were going to be terminated on February 28th?

A I received a text message over Microsoft Teams from James McElroy. He said, Liza -- something to the effect of: Liza, can you please get in touch with Rachel Riley ASAP, she's been trying to reach you.

I'm paraphrasing.

I said, James, I'm sorry, I do not know who Rachel Riley is. And then shortly thereafter, James called me over a Microsoft Teams video call, and so he was there and Rachel Riley was there. She introduced herself as being part of DOGE, who was working with HHS.

And she informed me that a number of grants will need to be terminated and that Matt Memoli will be sending me an e-mail, a list of grants in an e-mail shortly thereafter.

Q Did she explain why the grants were being terminated?

A No.

Q Did you ask?

A She explained that -- excuse me, let me

clarify.

She said that the current administration's OGC has a different opinion from the previous administration's OGC on grant termination and, therefore, we will need to terminate grants by the end of the day.

I did not ask what, you know, what grants because I just literally was a little bit confused and caught off guard. And so I waited to see what I would receive by e-mail.

Q And then what did you receive by e-mail?

A I received an e-mail from Matt Memoli that said something to the effect of: Liza, the attached list of grants need to be terminated by COB today. And there was an Excel file attached to the e-mail.

Q And did you look at the Excel file?

A Yes.

Q And can you describe it for me.

A It was a list of grants -- well, you know, I'm trying -- I don't exactly remember all of the cells in the Excel file, but it was a list of grants. I can't remember if it had the grant numbers, the titles, the institutions. It had some combination.

Q Did it give any reason why the grants were

Case: 25-1611 Case 1:25-cv-10787-BEM Document 38-16 Date Filed: 04/25/2025 Page: 2 of 39 ID: 6756750

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National Institutes of Health

Minority Health and Health Disparities Strategic Plan 2021–2025

Taking the Next Steps

NIH National Institutes of Health
Turning Discovery Into Health

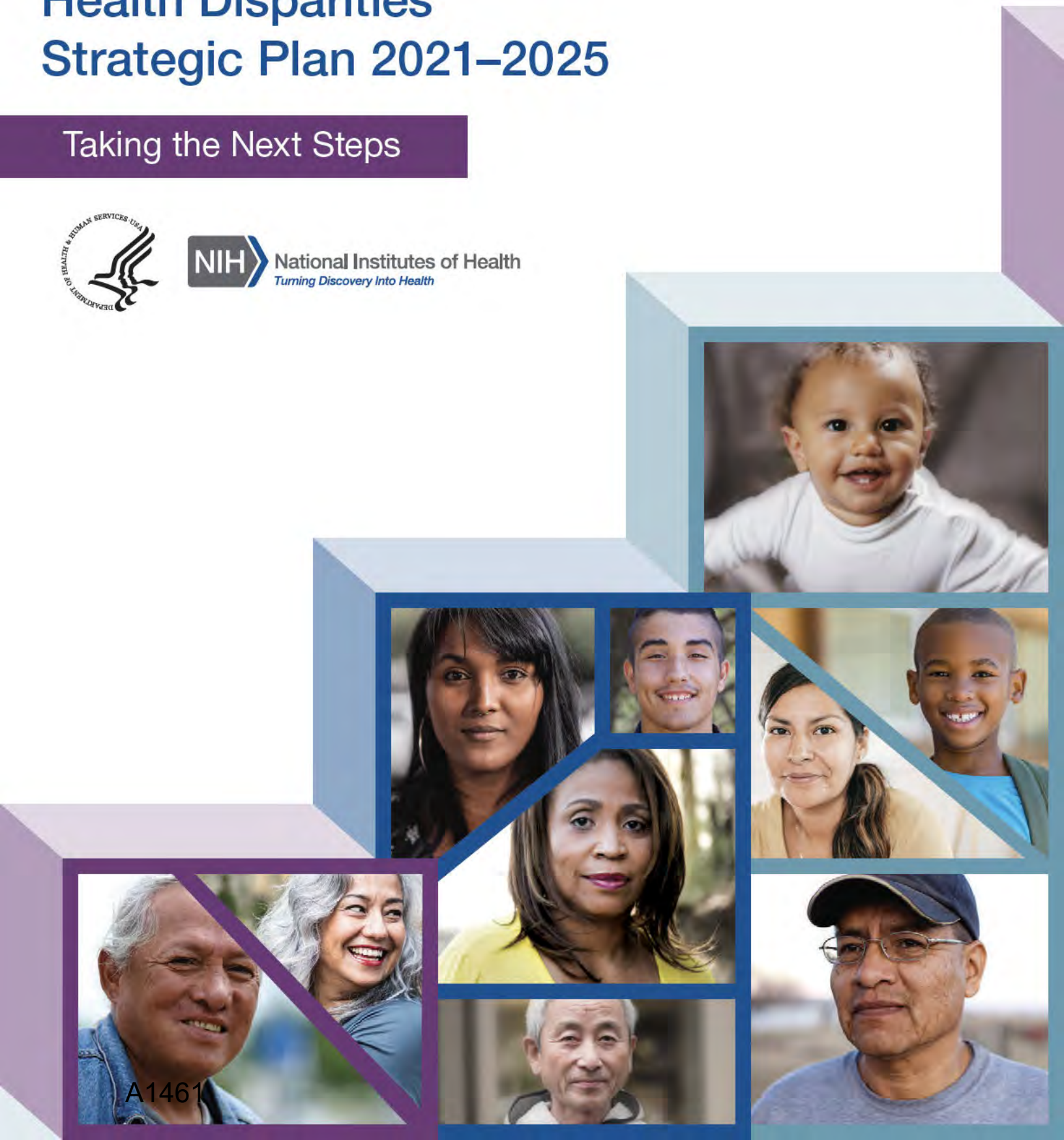

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Table of Contents

NIH Director's Foreword 3
Introduction 4
Minority Health and Health Disparities: Definitions and Parameters 6
NIH and HHS Commitment 8
Foundation for Planning 9
Structure of This Plan 10
Strategic Plan Categories 11
- Scientific Research 11
- Research Sustaining 11
- Outreach, Collaboration, and Dissemination 12
- Leap Forward Research Challenge 12

Summary of Categories and Goals 13
- Scientific Research Goals and Strategies 13
- Research-Sustaining Activities: Goals and Strategies 14
- Outreach, Collaboration, and Dissemination Goals and Strategies 14

Details of Categories and Goals 16
- Scientific Goals, Research Strategies, and Priority Areas 16
- Research-Sustaining Activities: Goals, Strategies, and Priority Areas 23
- Outreach, Collaboration, and Dissemination: Goals and Strategies 28

Leap Forward Research Challenge 32
- Minority Health and Health Disparities Research 33
- Research-Sustaining Goals 35

Future Plans 37

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NIH Director's Foreword

"Advancing the science of understanding the causes of health disparities and of developing effective interventions to reduce health disparities and improve minority health is one of my personal priorities. NIH has a major role in identifying interventions and causes of health disparities. If we can chip away at health disparities, everyone can experience the better health they deserve. Using the tools of research and our creativity to address our task, we have a moral responsibility to address health disparities. What a privilege to be engaged in this noble enterprise that has real promise to give every person the opportunity to have better health."

— Francis S. Collins, M.D., Ph.D., Director of NIH

"As health disparities remain a potentially preventable burden, public health is impacted unnecessarily."

— Eliseo J. Pérez-Stable, M.D., Director of the National Institute on Minority Health and Health Disparities, NIH

The publication of the Institute of Medicine report on unequal treatment, ***Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care***, summarized a legacy of unequal health care and differential health outcomes for most leading causes of disability and death in the United States among African Americans compared with Whites, with selected available data on other racial and ethnic minority groups. Since then, sources of data dramatically have improved while scientific advances in basic mechanisms have strengthened our understanding of etiological pathways and potential intervention points to improve minority health, reduce health disparities, and promote health equity. The need for rigorous scientific approaches to minority health and health disparities—building on decades of studies addressing social inequality and health, behavioral epidemiology, and access to quality health care—is now increasingly being met by an expanding array of biological and data science tools that help us understand health and disease mechanisms.

The Office of Minority Health Research was founded at NIH in 1990 to provide a focus for research questions that addressed racial/ethnic minority populations. Through congressional legislation, the Office was upgraded to the National Center on Minority Health and Health Disparities in 2000 and to the National Institute on Minority Health and Health Disparities (NIMHD) in 2010. NIMHD is charged with coordinating and leading NIH's vision and programs on minority health and health disparities research. The topics are broad and include health determinants pertaining to the entire life course, including all populations, diseases, prevention, and health care. Research that advances understanding and improvement of health and disease in minority racial/ethnic groups in the United States requires a basic understanding of the construct of race and ethnicity, incorporating the social determinants of health in the context of science. Research to understand the causes of and define mechanisms leading to interventions to reduce health disparities is a parallel mandate, incorporating socioeconomic, geographic, and cultural factors to address conditions with negative outcomes in specific populations. NIMHD envisions an America in which all populations will have an equal opportunity to live long, healthy, and productive lives.

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Introduction

Medical advances and new technologies have allowed Americans to live longer and healthier lives for the past century. These advances, however, have not helped all Americans equally, and health disparities persist, disproportionately affecting racial and ethnic minority populations, individuals of less privileged socioeconomic status (SES), underserved rural residents, sexual and gender minorities (SGMs),[1] and any subpopulations that can be characterized by two or more of these descriptions. In October 2016, SGMs were formally designated as a health disparity population for research purposes.

In the 35 years since the Heckler report was published,[2] pioneering researchers studying health disparities and minority health have worked to reduce the burden of premature illness and death experienced by many people from minority racial and ethnic backgrounds, SGMs, rural residents, and individuals of less privileged SES. For example, thanks to the efforts of researchers, advocates, and other stakeholders, the gap in mortality between Blacks and Whites was reduced by about half from 1999 to 2015, narrowing from 33 percent to 16 percent.[3] Not all health outcomes are worse for disparity populations; in selected conditions, racial and ethnic minorities of less privileged SES have better health.[4] However, the individuals comprising these groups still face considerable health disparities in most conditions. These disparities include shorter life expectancy; higher rates of cardiovascular disease, cancer, diabetes, infant mortality, stroke, cognitive impairment, asthma, sexually transmitted infections, and dental diseases; and differences in prevalence and outcomes of mental illness.

Health disparities are the result of differences in and interplay among numerous determinants of health, including biological factors, the environment, health behaviors, sociocultural factors, and the way health care systems interact through complex multilevel pathways. These dynamic and complex interactions lead to poor health outcomes and challenge researchers to identify mechanistic pathways to develop interventions that may lead to reductions in health disparities and improvements in minority health that promote health equity with a systematic applied approach.

Section 10334 of **P.L. 111-148** tasks NIMHD with coordinating NIH's research related to minority health and health disparities: "The Director of the Institute, as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review, and evaluate research and other activities conducted or supported by the Institutes and Centers of the National Institutes of Health." In addition, Section 2038 of P.L. 114-255 (21st Century Cures Act) tasks NIMHD with fostering partnerships and collaborative projects relating to minority health and health disparities: "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities." As part of all strategic planning processes across NIH, Institutes and Centers (ICs) are tasked with coordinating with the Directors of NIMHD and the Office for Research on Women's Health to ensure that the plans account for the unique perspectives, strengths, and challenges facing minorities and women, as described in Section 2031 of P.L. 114-255. Furthermore, section 404N of the Public Health Service Act encourages increased research with SGM populations as a response to the mounting evidence of the health disparities experienced by SGM populations, as well as an acknowledgment of unique

1 Sexual & Gender Minority Research Office (SGMRO). **Strategic Plan to Advance Research on the Health and Well-being of Sexual & Gender Minorities: Fiscal Years 2021–2025.**

2 Heckler MM. **Report of the Secretary's Task Force on Black and Minority Health.** U.S. Department of Health and Human Services.

3 Cunningham TJ, Croft JB, Liu Y, Lu H, Eke PI, Giles WH. **Vital Signs: Racial Disparities in Age-Specific Mortality Among Blacks or African Americans — United States, 1999–2015.** MMWR Morb Mortal Wkly Rep 2017;66:444–456.

4 Franzini L, Ribble JC, Keddie AM. **Understanding the Hispanic Paradox.** Ethn Dis. 2001;11(3):496-518.

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health challenges faced by SGM individuals who may be affected by a socially disadvantaged position. The plan will guide NIH in setting scientific goals, such as advancing the scientific understanding of health disparities, and research-related activity goals, such as strengthening the national research capacity to address minority health and health disparities.

Research supported by NIH has worked to reduce these disparities and improve minority health across all diseases, disorders, and conditions. As a result, all ICs contribute to the science and support activities. NIH also supports training, workforce development, capacity building, and other activities that work to reduce health disparities. This NIH strategic plan demonstrates ICs' commitment to research that improves minority health and reduces health disparities and to activities like training and capacity building that enhance the ability to reveal the new scientific knowledge needed to improve health for all Americans.

The scientific information discovered in basic research proposes to move along a continuum through clinical sciences until a practice or procedure that improves individual and population health can be implemented. Minority health and health disparities research can be viewed in a similar framework. Information about a racial or ethnic minority group—such as behavioral, biological, sociocultural, socio-ecological, and environmental characteristics and attributes—placed within a health care or public health setting provides the basis for understanding minority health. Once these basic factors are identified, similarities and differences between population groups may become apparent. These population differences may or may not constitute a health disparity, since the outcome for some conditions may be better for the population presumed to be disadvantaged, such as in the Hispanic Paradox.[5]

Understanding why a racial or ethnic minority group has a specific health outcome is at the core of minority health science. Minority health research intends to identify factors contributing to health conditions, independent of whether a health disparity exists or is identified. When investigations of differences in health between diverse groups exist, where the disadvantaged population group has a worse health outcome, this defines one aspect of health disparity research. Health disparity research then strives to understand mechanisms as to why a racial or ethnic minority group has a worse health outcome compared to a reference group.

Clarifying the difference between minority health and health disparities research prompted NIMHD to develop revised definitions for the biomedical research field. These distinct definitions provide justification for a new approach for the next generation of knowledge discovery to improve minority health and reduce health disparities.

5 Ruiz JM, Steffen P, Smith TB. **Hispanic mortality paradox: a systematic review and meta-analysis of the longitudinal literature.** Am J Public Health. 2013;103(3):e52-e60.

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Minority Health and Health Disparities: Definitions and Parameters

Definitions of the terms "minority health" and "health disparities" have evolved as the research fields have grown and interacted with the full spectrum of scientists. Initially, the definitions were intertwined, as the researchers doing this important work have bridged both fields, and the assumption was made that minority populations always had health disparities. For NIH, this plan underscores the need to separate the science of minority health, which focuses on the health of racial and ethnic minority communities, and the science of health disparities, which focuses on differences in health outcomes for defined disadvantaged populations that are worse than the White reference population. There is clear overlap, since for many conditions, minority populations have well-defined health disparities compared with the White population in the United States. However, creating some separation of these disciplines may prove beneficial in enabling each field to make greater independent strides. Over the course of fiscal years (FYs) 2015 and 2016, NIMHD undertook a process across NIH to revise the definitions for minority health and health disparities.[6]

Minority Health Definition

Minority health (MH) refers to the distinctive health characteristics and attributes of racial and/or ethnic minority groups, as defined by the U.S. Office of Management and Budget (OMB), that can be socially disadvantaged due in part to being subject to potential discriminatory acts.

Minority Health Populations

NIH uses the racial and ethnic group classifications determined by OMB in the Revisions to Directive 15, titled ***Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity***. The minority racial and ethnic groups defined by OMB are American Indian or Alaska Native, Asian, Black or African American, and Native Hawaiian or other Pacific Islander. The ethnicity used is Latino or Hispanic.

Although these five categories are minimally required, the mixed or multiple race category should be considered in analyses and reporting, when available.

Other NIH efforts that support Tribal Nations can be found in the ***NIH Strategic Plan for Tribal Health Research FY 2019–2023***.

Self-identification is the preferred means of obtaining race and ethnic identity.

Minority Health Research

Minority health research is the scientific investigation of distinctive health characteristics and attributes of minority racial and/or ethnic groups who are usually underrepresented in biomedical research to understand health outcomes in these populations.

Health Disparity Definition

A health disparity (HD) is a health difference that adversely affects disadvantaged populations, based on one or more of the following health outcomes:

- Higher incidence and/or prevalence and earlier onset of disease
- Higher prevalence of risk factors, unhealthy behaviors, or clinical measures in the causal pathway of a disease outcome
- Higher rates of condition-specific symptoms, reduced global daily functioning, or self-reported health-related quality of life using standardized measures
- Premature and/or excessive mortality from diseases where population rates differ
- Greater global burden of disease using a standardized metric

6 **AJPH Supplement: New Perspectives to Advance Minority Health and Health Disparities Research.** Am J Public Health. 2019;109(S1).

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Health Disparity Populations

NIH defines health disparity populations as racial and ethnic minority populations (see above OMB directive), less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM), and any subpopulations that can be characterized by two or more of these descriptions.

Other NIH efforts that support SGMs can be found in the ***NIH FY 2016–2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities***.

Health Determinants

There are many factors that impact an individual's health and the risk of experiencing health disparities. These domains of influence have been expanded into "health determinants" in order to capture areas that go beyond the social determinants and that include factors, such as individual behaviors, lifestyles, and social responses to stress; biological processes, genetics, and epigenetics; the physical environment; the sociocultural environment; social determinants; and clinical events and interactions with the health care and other systems. Each of these health determinants plays an important role in health disparities and interacts in complex ways to affect an individual's health. For example, African American/Black women and Latinas experience lower survival rates from triple-negative breast cancer than White women with the same disease—even with similar access to care, screening mammography, and insurance coverage—due to the lack of specialized screening and lack of viable treatment options available for this form of breast cancer.[7]

7 Ko NY, Hong S, Winn RA, Calip GS. **Association of Insurance Status and Racial Disparities With the Detection of Early-Stage Breast Cancer.** JAMA Oncol. 2020;6(3):385–392.

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NIH and HHS Commitment

Healthy People 2020 envisions a society in which all people live long, healthy lives. The U.S. Department of Health and Human Services (HHS) aims to enhance the health and well-being of all Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. In April 2011, HHS released the ***HHS Action Plan to Reduce Racial and Ethnic Health Disparities*** (*HHS Disparities Action Plan*), a comprehensive national strategy to reduce health disparities. The HHS Disparities Action Plan sets out five goals to help achieve the vision of a nation free of disparities in health and health care.

The mission of NIH, as part of HHS, 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. In 2015, NIH released the ***NIH-Wide Strategic Plan, Fiscal Years 2016–2020***, outlining a vision for biomedical research that capitalizes on new opportunities for scientific exploration and addresses new challenges for human health. The *NIH Minority Health and Health Disparities Strategic Plan* also aligns with the health promotion and disease prevention objective of the *NIH-Wide Strategic Plan* by advancing opportunities in biomedical research through evidence-based reduction of health disparities.

The *NIH Minority Health and Health Disparities Strategic Plan* follows the missions and goals outlined in these plans and addresses the current insufficient progress in improving MH and reducing HDs in the United States. The plan integrates NIMHD's vision of an America in which all populations have equal opportunity to live long, healthy, and productive lives with NIH's mission to seek fundamental knowledge of the nature and behavior of living systems and apply new knowledge to enhance health, lengthen life, and reduce illness and disability.

The *NIH Minority Health and Health Disparities Strategic Plan* represents a commitment by NIH to support research aimed at addressing the risk and protective factors that operate and interact on multiple levels to impact the well-being of HD populations. NIH is also committed to supporting research-sustaining activities—such as research capacity building, workforce development, outreach, and inclusion of minorities in clinical trials—that improve MH and reduce HDs, as well as activities that promote collaboration and dissemination in different fields.

The *NIH Minority Health and Health Disparities Strategic Plan* aligns NIH's efforts to address MH and HDs with advancing scientific knowledge and innovation in the HHS Disparities Action Plan.

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Foundation for Planning

This strategic plan was created with the input of several NIH working groups, including teams of staff and researchers. To ensure that stakeholders at multiple levels were involved in this strategic planning process, NIMHD gathered input from experts within and outside of NIH. A few of these foundational activities are described below.

- In FY 2012, during the Science of Eliminating Health Disparities summit, NIMHD conducted town hall meetings to collect data on critical minority health and health disparity research issues.
- In FY 2015, NIMHD led an analysis of NIH's portfolio of minority health and health disparities research to survey the status of both fields, analyze investments, and gauge gaps in the science or supporting structures.
- During FY 2015 and FY 2016, NIMHD undertook a science visioning process to produce recommendations for advancing the fields of minority health and health disparities. Participating NIH staff and outside stakeholders suggested 10 priority recommendations each in defining etiologies and mechanisms, developing and evaluating interventions, and identifying innovative methods from a wide range of needs, to reduce disparities and improve minority health. After review by the National Advisory Council on Minority Health and Health Disparities (NACMHD), the relevant recommendations were woven into the current strategic planning efforts, which include strategies beyond the visioning process and the Minority Health and Health Disparities Research Framework. Details are available in the *American Journal of Public Health (AJPH)* supplement ***New Perspectives to Advance Minority Health and Health Disparities Research***.
- During FY 2018, NIMHD held three virtual sessions and four listening sessions across the country to collect community-level input for the *NIH Minority Health and Health Disparities Strategic Plan*.

These activities—in coordination with NIH working groups and input from a range of NIH Institutes, Centers, and Offices—were reviewed by the National Advisory Council on Minority Health and Health Disparities (NACMHD) and provide the foundation for the *NIH Minority Health and Health Disparities Strategic Plan*.

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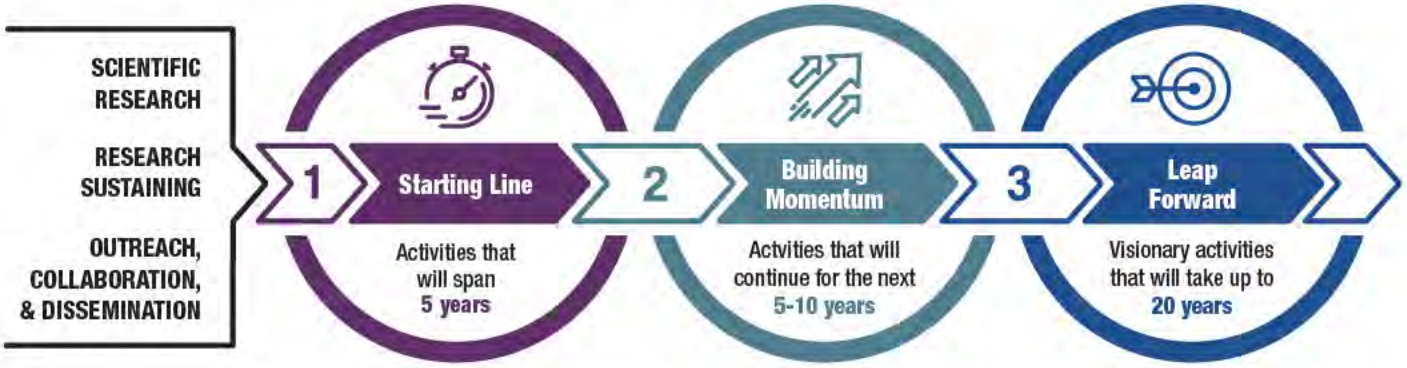
Structure of This Plan

FIGURE 1: NIH MH and HD Research Strategic Plan Priority Areas Framework



The NIH Minority Health and Health Disparities Strategic Plan 2021–2025 has been designed with three categories to represent a long-term framework: scientific research; research-sustaining activities; and outreach, collaboration, and dissemination to encompass the range of NIH's MH- and HD-related work. Embedded in each category are goals that encompass up to 10 years of expected research. There are four research goals; three research-sustaining activities goals; and two outreach, collaboration, and dissemination goals.

This plan describes scientific goals with related research strategies and priority areas that represent key opportunities and needs to advance MH and HD research. Rather than reflecting a comprehensive listing of all relevant NIH activities, this plan describes how NIH can best advance minority health and health disparities research. Each goal is divided into strategies that are intended to capture strategic ways in which NIH can advance the sciences of MH and HD or develop key supporting structures. The priority areas consist of Starting Line and Building Momentum research efforts and activities that encompass MH and HD efforts across NIH. This plan includes 48 Starting Line activities that will span 5 years and 56 Building Momentum activities that will continue for the next 5 to 10 years (see Figure 1).

Eliminating health disparities is an indefinite priority for NIH, and NIH's efforts in this space will continue well into the future. This plan lays out a focused vision for the next 10 years, specifying short-, intermediate-, and long-range research strategies and activities that will facilitate progress toward long-term goals.

These priority areas are described below:

- **Starting Line** priority areas represent concrete, current efforts and initiatives aimed at improving minority health and/or reducing health disparities that are underway at NIH or with NIH partners.
- **Building Momentum** priority areas represent concepts and potential initiatives for advancing the sciences of minority health and health disparities. These concepts include early ideas and initiatives being developed and considered for potential implementation.
- **Leap Forward** priorities represent trans-NIH visionary goals that can have a significant impact on improving minority health or reducing health disparities in disease and disorders.

The *NIH Minority Health and Health Disparities Strategic Plan 2021–2025* includes performance tracking and evaluation components to meet federal requirements. Most importantly, the plan aims to advance the science of minority health and health disparities and produce meaningful, measurable improvements in minority health and reductions in health disparities through the dissemination and implementation of both existing and novel scientific breakthroughs over the duration of the strategic plan and beyond.

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Strategic Plan Categories

Scientific Research

Scientific research encompasses the continuum of research activities, from basic through applied research. Research is systematic study directed toward advancing scientific knowledge and/or gaining understanding of etiology and interventions to improve minority health and/or to reduce health disparities. This section also focuses on the need to strengthen and promote analytic methods that will enable a better understanding of the indicators and underlying causes of health disparities and facilitate ongoing monitoring.

Research Sustaining

Beyond conducting research, NIH also promotes the strengthening and expansion of structures that support research throughout the scientific process. NIH supports a variety of training programs, including those that work to promote diversity of the national biomedical workforce and those that work to increase the number of scientists studying minority health and health disparities. NIH also supports strengthening the national research capacity for minority health and health disparities research, capacity building for institutions that offer doctoral degrees in the health professions or the sciences related to health and have a historical and current commitment to educating underrepresented students, and programs to facilitate their inclusion in biomedical research. These activities are essential components of NIH's minority health and health disparities research-sustaining activities.

- **Biomedical Workforce Diversity**
  The overall composition of the biomedical workforce—not just individuals' skills—plays a role in its effectiveness. The Notice of NIH's Interest in Diversity (NOT-OD-20-031) states, "Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in and benefit from health research, and enhancing public trust."

- **Minority Health and Health Disparities Scientific Workforce**
  As the sciences of minority health and health disparities become more complex, the need for scientists with expertise in minority health and health disparities issues and for collaboration in a multidisciplinary team must be addressed. Recruitment, training, and retention of investigators with state-of-the-art skill sets in minority health and health disparities science are essential, throughout all stages of career development.

- **Research Capacity Building**
  The fields of minority health and health disparities research are growing, requiring greater academic infrastructure. NIH continues to strengthen programs and initiatives aimed at building scientific infrastructure and capacity at academic institutions and other organizations to support research in minority health and health disparities. These activities will help to develop vibrant communities of researchers to move both fields forward.

- **Including Racial and Ethnic Minorities and SGM Populations in Clinical Research Involving Human Participants**
  NIH is committed to ensuring that individuals who identify as racial and ethnic minorities, SGMs, and women are included in clinical research. This plan suggests additional actions intended to ensure that appropriate and meaningful representation occurs in NIH-funded research.

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Identifying and addressing the barriers to inclusion of minorities (i.e., racial and ethnic and other HD populations, such as SGMs) in clinical research and developing tools to help researchers enhance minority recruitment should facilitate efforts to promote minority health and reduce health disparities. Furthermore, NIH-funded investigators need to be held accountable for proposed recruitment targets when launching research studies with human participants. Including minority populations in clinical studies and data sets is critical to ensure that people from all racial and ethnic backgrounds and other HD populations share in the benefits of new scientific discoveries.

Outreach, Collaboration, and Dissemination

NIH supports outreach, collaboration, and dissemination efforts that are needed to ensure that key MH and HD research findings are shared with the people and communities that need them. This plan focuses on expanding community outreach and enhancing dissemination efforts, as well as building community to enhance networks of MH and HD researchers and stakeholders across the nation and within NIH.

- **Outreach and Dissemination**
  Promoting the capacity to translate research findings into recommendations to be implemented in clinical and public health practice is essential for reducing health disparities. NIH can support appropriate stewardship by considering factors related to dissemination of MH and HD research at every stage of the research process. These efforts are needed to ensure that evidence-based interventions become part of established, everyday practice and integrated into the public health process.

- **Community Engagement and Building**
  As part of the outreach and dissemination process, broadening and strengthening the community of minority health and health disparities stakeholders—including health disparity communities, researchers, clinicians, advocacy groups, government employees, and policy makers—expands the potential avenues for collaboration and progress toward evidence-based practice and policy. This plan offers strategies for engaging and enhancing MH and other HD communities at multiple levels to help support the research of both fields.

Leap Forward Research Challenge

Leap Forward priority areas are expected to have a significant impact on advancing the field of minority health and health disparities research over the next 10 to 15 years. NIH challenged itself and the research community to be bold and strive for transformational progress across the continuum of research in minority health and health disparities. Leap Forward priority areas represent aspirational activities that NIH hopes to embark upon to improve minority health or to reduce a health disparity in scientific research and in research-sustaining activities.

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Summary of Categories and Goals

Scientific Research: Goals and Strategies

Goal 1: Promote research to understand and to improve the health of racial/ethnic minority populations

- **Strategy 1.1:** Examine health determinants that underlie resilience or susceptibility to diseases and conditions experienced by minority populations.
- **Strategy 1.2:** Develop and assess interventions to improve the health status of minority populations.

Goal 2: Advance scientific understanding of the causes of health disparities

- **Strategy 2.1:** Investigate health determinants through basic, behavioral, clinical, and applied research to better understand the contributions to health disparity outcomes.
- **Strategy 2.2:** Support research to explore multilevel pathways and dynamic interrelationships of health determinants that affect health disparity outcomes over the life course and across generations.
- **Strategy 2.3:** Identify relevant critical periods and feasible targets for health disparity interventions.

Goal 3: Develop and test interventions to reduce health disparities

- **Strategy 3.1:** Design and test interventions that target known health determinants within the context of specific populations and appropriate life course time points to influence specific health disparity outcomes.
- **Strategy 3.2:** Embed implementation science within intervention studies to inform efforts to scale, sustain, and translate efficacious interventions within and across populations and settings.
- **Strategy 3.3:** Promote prevention and evaluate the impact of upstream interventions on distal health disparity outcomes across the lifespan and across generations.

Goal 4: Create and improve scientific methods, metrics, measures, and tools that support health disparities research

- **Strategy 4.1:** Identify and test the adoption of common indicators to quantify the status of health disparities across different diseases/conditions and populations.
- **Strategy 4.2:** Define the continuum from health differences to health disparities, both qualitatively and quantitatively across multiple dimensions, as well as develop contextually informed clinical and statistical measures of disparities reductions.
- **Strategy 4.3:** Apply complex systems modeling approaches, including biological models, to identify and predict relationships between health determinants and health disparity outcome measures.
- **Strategy 4.4:** Support movement toward standardization, collection, reporting, and leveraging of measures of health determinants in both existing and emerging data sources, including administrative clinical data, to foster linkages between health, sex and gender, and relevant health determinants data for use in identifying health disparities and underlying causes through emerging techniques found in data science.
- **Strategy 4.5:** Identify and strengthen rigorous quantitative and qualitative methods to enable analysis on small populations and subpopulations.
- **Strategy 4.6:** Evaluate minority health and health disparities proposals, programs, and policies to assess the effectiveness in improving minority health and/or reducing health disparities.

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Research-Sustaining Activities: Goals and Strategies

Goal 5: Support training to enhance diversity and to promote training and career advancement of minority health and health disparities researchers

Workforce Diversity

- **Strategy 5.1:** Support individual-level programs to train individuals from health disparity populations in the biomedical sciences.
- **Strategy 5.2:** Support current and novel institution-level programs at institutions that have a historical and current commitment to educating underrepresented students and at less research-intensive institutions to enhance the ability of these programs to recruit, train, and retain a diverse biomedical research workforce.
- **Strategy 5.3:** Promote diversity-supporting recruiting programs at research-intensive institutions to expand the pool of applicants from health disparity groups underrepresented in biomedical research.

Minority Health and Health Disparities Scientific Workforce

- **Strategy 5.4:** Support training and mentorship programs for minority health and health disparities researchers at all stages of career development and leadership development.
- **Strategy 5.5:** Incorporate development of specialized research skills into health disparities training programs, including core and emerging skills that are important for measuring, understanding, and identifying solutions to address minority health and health disparities complexities.

Goal 6: Strengthen the national capacity to conduct minority health and health disparities research

- **Strategy 6.1:** Support programs to enhance capacity for minority health and health disparities research at institutions of all sizes.
- **Strategy 6.2:** Develop and test methods to foster, coordinate, and promote the field of health disparities among research institutions and organizations.

Goal 7: Ensure appropriate representation of minority and other health disparity populations in NIH-funded research

- **Strategy 7.1:** Provide guidance, recommendations, and technical assistance for NIH-funded researchers in appropriate study design and best practices for recruitment to ensure compliance with laws, regulations, and policies regarding the inclusion of minorities and other health disparity populations in research.
- **Strategy 7.2:** Promote and enforce accountability for inclusion of diverse populations by tracking originally proposed recruitment strategies and objectives to ensure sufficient samples for analyses of subpopulation data.
- **Strategy 7.3:** Promote inclusion of minorities and other health disparity populations in big data sets, clinical research, and future big science initiatives.

Outreach, Collaboration, and Dissemination: Goals and Strategies

Goal 8: Promote evidence-based community engagement, dissemination, and implementation of minority health and health disparities research best practices

- **Strategy 8.1:** Develop and test best practices for dissemination and implementation of minority health and health disparities research discoveries into different settings and with different populations.
- **Strategy 8.2:** Conduct studies to determine strategies for effective population-specific communication and outreach to inform recruitment and retention into clinical research studies and databases, design of culturally tailored health interventions, and community engagement and participation in research.
- **Strategy 8.3:** Generate strategies and tools to transform minority health and health disparities best practices into policies.

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Goal 9: Cultivate and expand a community of minority health and health disparities researchers and advocates

- **Strategy 9.1:** Build an NIH interdisciplinary community of scholars around minority health and health disparities research to coordinate disparities science and to foster accountability and integration of minority health and health disparities science within NIH research activities.
- **Strategy 9.2:** Promote interagency collaboration and coordination with federal departments and agencies, including use of common data elements (CDEs) and data sharing relevant to minority health and health disparities research.
- **Strategy 9.3:** Establish partnerships with nongovernmental groups (e.g., mentoring networks, advocacy groups, industry and private groups, science communities, grantees) to advance the development, improvement, and utilization of minority health and health disparities definitions, methods, measures, metrics, interventions, and best practices.

Case: 25-1 Case 1:25-cv-10787-BEM Document: 38-16 Filed: 04/25/2025 Page: 17 Date Filed: 04/25/2025 Page 17 of 139 ID: 6756750

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DETAILS OF CATEGORIES AND GOALS

SCIENTIFIC GOALS, RESEARCH STRATEGIES, AND PRIORITY AREAS

There are challenges measuring health disparities, including identifying how to measure the health disparity and selecting appropriate benchmark populations. The following scientific goals and research strategies focus on measurement to provide solutions to these obstacles and advance minority health and health disparities research.

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GOAL 1: Promote research to understand and to improve the health of racial/ethnic minority populations

This goal advances the understanding of health determinants that contribute to the health status of minority populations, including subpopulations. Scientific knowledge generated should span the life course and address sociocultural variations and within-group differences. As the understanding of the interplay between biology and environment advances, better interventions can continue to be developed to improve the health of minority groups. In addition, research into the determinants that affect minority health may lead to new knowledge about the health differences experienced by minority groups.

STRATEGY 1.1: Examine health determinants that underlie resilience or susceptibility to diseases and conditions experienced by racial/ethnic minority populations.

ACTION PRIORITY AREAS

Starting Line:

- Expand support for large-scale observational, epidemiologic, and longitudinal cohort studies focused on multiple co-occurring chronic diseases and conditions in minority populations.
- Support ancillary etiologic studies using existing cohorts to examine the interplay between biological, behavioral, socioecological, sociocultural, and environmental health determinants in minority populations, as well as interactions with health care and public health systems.
- Support interdisciplinary minority health studies to delineate mechanisms of embodiment of social, cultural, and environmental factors experienced over the life course to better understand how those factors influence individual early development, physiology, cognitive processes, biopsychosocial processes and behavior, and disease trajectories.

Building Momentum:

- Support research, including international research, to identify genomic factors that contribute to U.S. racial and ethnic differences in health outcomes.
- Support research to identify key developmental origins or stages of susceptibility to common diseases and conditions or exposures where interventions would most likely have the greatest effect.
- Expand research efforts to delineate risk factors for developing obesity in early childhood and adolescence as well as identify opportunities for developing more effective and contextually tailored interventions.
- Accelerate efforts to define the critical contributions of oral health to overall health and disease in minority populations through studies to identify genetic and genomic risk or protective factors that contribute to racial and ethnic differences in health outcomes, mediating or moderating influences of the microbiome, diet and nutrition, access to preventive dental and health care across the life course, and co-occurring chronic diseases and conditions.
- Expand support for research to identify sociocultural factors and other positive resources that promote population health and contribute to resiliency at the individual, family, and community levels.
- Support oversampling of racial/ethnic minority participants in population-based and patient-oriented studies to increase power to detect hypothesized racial/ethnic differences and enable analysis and comparison of racial/ethnic subpopulations.

STRATEGY 1.2: Develop and assess interventions to improve the health status of minority populations.

ACTION PRIORITY AREAS

Starting Line:

- Develop and implement individual-, family-, peer group-, and community-level health promotion and disease prevention interventions tailored to address the specific needs and cultural contexts of minority populations.
- Develop and implement evidence-based health care system interventions that reduce socioecological barriers to care and promote coordination and integration of preventive care, primary care, and behavioral health services.

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- Support secondary data analyses of ongoing cohort studies and public use surveys, as well as other approaches such as simulation modeling, to determine whether minority health differences observed in population studies reflect health disparities arising from social, economic, and/or environmental disadvantages based on group characteristics historically linked to discrimination or exclusion.

Building Momentum:

- Establish a national consortium to develop, validate, and implement assessment tools that can be used in primary care settings for early detection and diagnosis of cognitive impairment and decline, as well as Alzheimer's disease and related dementias, which are frequently underdiagnosed in aging minority populations, often due to cultural and logistic barriers.
- Expand research to improve access to and coordination of health care services across specialties through innovative care delivery models and the use of health information technology, including research on the use of electronic health records (EHRs) and e-prescribing databases to address potential risks of adverse drug reactions and drug–drug interactions in minority patient populations.
- Support rigorous research on patient–clinician communication factors in primary care and specialty settings that lead to an increase or decrease in health disparities in patient outcomes.
- Support rigorous evaluation of community-engaged interventions to address gaps and improve implementation of evidence-based interventions in community settings and to better understand factors that influence intervention effectiveness and adaptability.
- Support innovative research incorporating strengths-based approaches, behavioral economics principles, and multilevel intervention strategies to promote overall health in disadvantaged minority populations and reduce the incidence of preventable diseases and conditions in early childhood, such as dental decay and overweight/obesity.
- Expand local, regional, and national efforts to assess the impact of policies and policy changes on racial/ethnic minority population health and delineate specific mechanisms by which policies or policy changes mitigate or exacerbate social, economic, and environmental disadvantages.
- Strengthen the capacity of community members, health professionals, policy makers, and community organizations to assess and utilize research findings to effect positive, systemic changes to reduce health disparities.

GOAL 2: Advance scientific understanding of the causes of health disparities

This goal seeks to examine the etiology of health disparities and the influence of health determinants on various stages of the life course trajectories and across generations, including the intersection of sex, gender, geography, and race and ethnicity. It also seeks to further the scientific understanding of both the individual effects on health disparities and the complex interactions among health determinants that affect health disparities. These health determinants include both studied and unstudied determinants as well as known and unknown determinants. Research is needed to identify and better understand the integrated relationship of these determinants, especially in real-world settings. These complexities often require interdisciplinary systems science approaches to understand interactions among multiple factors and over time. Results from such research should provide a robust foundation for designing effective interventions to reduce health disparities.

STRATEGY 2.1: Investigate health determinants through basic, behavioral, clinical, and applied research to better understand the contributions to health disparity outcomes.

ACTION PRIORITY AREAS

Starting Line:

- Identify risk factors that act as health determinants in creating and/or sustaining health disparity outcomes for NIH-designated health disparity populations.

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Building Momentum:

- Support research that seeks mechanisms and pathways behind health determinants that confer worse outcomes in health disparity populations and identify feasible intervention targets for health disparity outcomes.
- Identify disparities in understudied health disparity populations—for example, sexual and gender minorities (SGMs) and Native Hawaiians and other Pacific Islanders.
- Support research in understudied health conditions and risk factors that affect health, such as comorbidities and/or violence, that disproportionately affect health disparity populations.

STRATEGY 2.2: Support research to examine multilevel pathways and dynamic interrelationships of health determinants that affect health disparity outcomes over the life course and across generations.

ACTION PRIORITY AREAS

Starting Line:

- Explore associations between established determinants of health disparity outcomes occurring at multiple levels (e.g., environmental, health care, sociocultural, biological) to identify mechanisms and pathways for health disparity outcomes.

Building Momentum:

- Examine how health disparities develop or are sustained over the life course and across generations.
- Replicate mechanistic and pathway analyses of determinants for additional, related health outcomes, health disparity populations, and life course approaches and/or across generations.
- Support the collection of diverse ancestral backgrounds in NIH-funded and analyzed -omics data sets to achieve representation similar to the U.S. population.

STRATEGY 2.3: Identify modifiable or reversible determinants of health disparities during relevant critical periods that can serve as feasible targets for health disparity interventions.

ACTION PRIORITY AREAS

Starting Line:

- Link data on environmental, health care, sociocultural, behavioral, and/or biological health determinants in racial, ethnic, socioeconomically, sexual identity, geographically, and ancestrally diverse cohorts to existing systems for specific outcome ascertainment (e.g., hospitalizations, incidence of specific conditions, mortality, emphasizing life course, age cohort perspectives).

Building Momentum:

- Support research that enables culturally relevant and appropriate interventions to disrupt fundamental determinants at critical periods that produce health disparity outcomes for priority populations.

GOAL 3: Develop and test interventions to reduce health disparities

This goal advances the development and testing of population-specific interventions that reduce adverse health differences and poor health outcomes. This research should capitalize on existing evidence on health determinants to develop interventions that are culturally appropriate and develop new evidence, drawing on research from many different scientific disciplines. Health disparities can include biological, behavioral, sociocultural, environmental, and health care system–level factors. The interventions should be intentional about which populations, time points in the life course, and risk or protective factors are targeted for reduction of health disparity outcomes. Implementation science methods should be employed to inform feasibility, generalizability, and validity assessments of efficacious interventions.

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STRATEGY 3.1: Design and test interventions that target known health determinants within the context of specific populations and appropriate life course time points to influence specific health disparity outcomes.

ACTION PRIORITY AREAS

Starting Line:

- Adapt evidence-based interventions for implementation and evaluation within health disparity populations in culturally appropriate ways that consider the role of cultural processes in health disparity outcomes.
- Develop and test interventions that target multiple socioecological levels at appropriate life course time points to improve health disparity outcomes within community-based populations.

Building Momentum:

- Design and test strategies to improve access to and quality of care for health disparity populations within the health care system.
- Assess the implementation of interventions within clinical system processes and settings, and determine the effects on health disparity outcomes and populations.
- Develop and test interventions to improve symptom self-management and health-related quality-of-life outcomes in health disparity populations experiencing chronic and overlapping health conditions.

STRATEGY 3.2: Embed implementation science within intervention studies to inform efforts to scale, sustain, and translate efficacious interventions within and across populations and settings.

ACTION PRIORITY AREAS

Starting Line:

- Develop and test practical and sustainable adaptations within routine health care settings to improve health disparity outcomes and enable dissemination of effective practices.
- Incorporate elements of implementation and scalability into the design and testing of interventions to enhance related effectiveness in real-world settings, particularly low-resource clinical and community settings that serve health disparity populations.

Building Momentum:

- Develop guidance for NIH-supported researchers conducting intervention studies to include analyses of the pathways and mechanisms by which health disparity interventions produce observed effects.
- Use implementation science approaches to understand and promote the adoption of evidence-based interventions to reduce health disparities.
- Expand research in areas of implementation science with emphasis on clinical and public health systems processes for delivering preventive and treatment interventions in health disparity populations.
- Develop criteria to assess whether interventions have sufficient evidence for demonstrating success, and create and maintain a compendium of evidence-based interventions with demonstrated success in reducing health disparities in the United States.

STRATEGY 3.3: Promote prevention and evaluate the impact of upstream interventions on distal health disparity outcomes across the lifespan and across generations.

ACTION PRIORITY AREAS

Starting Line:

- Develop, implement, and evaluate participatory multilevel interventions to reduce exposures to environmental factors for which exposures create adverse health effects in disadvantaged populations, and assess the impact on early biomarkers of associated chronic diseases and conditions.
- Develop and evaluate school-based prevention and health promotion interventions related to health behaviors and mental health.

Building Momentum:

- Promote research on the benefits of preventive interventions, including assessments of the long-term

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impact on direct measures of health, health-related outcomes, and inter-generational transmission of health disparities.

- Review available evidence to identify key gaps in prevention science related to health disparities, and promote targeted research on preventive services with the aim to increase population health equity.
- Develop and evaluate workplace-based prevention and health promotion interventions related to health behaviors and mental health.

GOAL 4: Create and improve scientific methods, metrics, measures, and tools that support health disparities research

The science of health disparities is a relatively new discipline, drawing on expertise from many different fields of study. This diversity of thought presents unique opportunities, allowing researchers to bring methodologies from all parts of academia to bear on reducing health disparities. Researchers have access to a variety of powerful methods, metrics, measures, and tools to identify when health disparities exist, what causes a disparity, and when a disparity is affected. This diversity can present a challenge, however, in understanding health disparities data across the field. Development and adaptation of common indicators, measures, and methods is needed to enable comparisons among populations, to quantify the roles of various health determinants in influencing and impacting a health disparity, and to promote interdisciplinary collaboration. Population-based data systems should include representative samples of minority and health disparity populations to facilitate methods development and testing.

STRATEGY 4.1: Identify and test the adoption of common indicators to quantify the status of health disparities across different diseases/conditions and populations.

ACTION PRIORITY AREAS

Starting Line:

- Compile measurement tools (surveys and administered tests) in non-English languages applicable to the region.
- Develop common standards for capturing data on health disparities, including health determinants that encompass social determinants, with support from the National Library of Medicine.

Building Momentum:

- Develop tools to measure health indicators for health disparities research.
- Develop measurement tools in non-English languages that can measure differences in population responses applicable to the region.

STRATEGY 4.2: Define the continuum from health differences to health disparities, both qualitatively and quantitatively across multiple dimensions, and develop contextually informed clinical and statistical measures of disparities reductions.

ACTION PRIORITY AREAS

Starting Line:

- Set priorities and a research agenda around health disparities measures and metrics.
- Determine the metric that can be established to standardize a disparity reduction.

Building Momentum:

- Collect and disseminate longitudinal data about specific health disparity conditions to develop measures of clinical change over time that apply to different subpopulations.

STRATEGY 4.3: Apply complex systems modeling approaches to identify and predict relationships between health determinants and health disparity outcome measures.

ACTION PRIORITY AREAS

Starting Line:

- Promote interdisciplinary collaboration among health researchers and experts in computational approaches to further the development of modeling- and simulation-based systems science methodologies.

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Building Momentum:

- Assess multilevel interventions in the context of these simulation modeling and systems science research projects.
- Develop innovative model systems to advance understanding of disabilities that can lead to disparities and inequities in access and utilization of health care, rehabilitation treatments, and knowledge of preventive measures.

STRATEGY 4.4: Support movement toward standardization, collection, reporting, and leveraging of measures of health determinants in both existing and emerging data sources, including administrative clinical data, to foster linkages between health, sex and gender, and relevant health determinants data for use in identifying health disparities and underlying causes through emerging techniques found in data science.

ACTION PRIORITY AREAS

Starting Line:

- Promote analysis and publication of research results that include relevant and appropriately sized samples from health disparity populations.

Building Momentum:

- Sponsor and support workshops that result in technical reports and publications related to specific measurement issues in health disparities research, such as statistical analysis of small samples, self-identified race and ethnicity, and ancestry informative markers.
- Review and compile major papers on measures and metrics in health disparities to create a repository of technical papers, tools, and publications.
- Identify a representative from NIMHD and the NIH-wide Minority Health and Health Disparities Measurement and Methods Committee to collaborate with NIH's Office of Data Science Strategy (ODSS) to facilitate the inclusivity and external validity of calculations and labels that affect health disparity populations.

STRATEGY 4.5: Identify and strengthen rigorous quantitative and qualitative methods to enable analysis on small populations and subpopulations.

ACTION PRIORITY AREAS

Starting Line:

- Foster methodologies for conducting small population analyses.

Building Momentum:

- Map the state of the science for qualitative and quantitative studies with small populations and subpopulations.
- Develop research agendas for health disparity measurement in small populations and subpopulations.

STRATEGY 4.6: Evaluate minority health and health disparities proposals, programs, and policies to assess the effectiveness in improving minority health and/or reducing health disparities.

ACTION PRIORITY AREAS

Starting Line:

- Develop educational materials for program officers, program analysts, evaluators, and policy analysts on measures, metrics, and their use in outcome assessments of health disparity research.

Building Momentum:

- Assess the effects of social policies on minority health and health disparities.
- Assess the impact of previous NIH grants that were identified as focusing on minority health and/or health disparities.

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DETAILS OF CATEGORIES AND GOALS

RESEARCH-SUSTAINING ACTIVITIES: GOALS, STRATEGIES, AND PRIORITY AREAS

Programs that promote diversity of biomedical workforce, enhance and strengthen the minority health and health disparities research workforce, and provide infrastructure for research capacity-building activities are needed. Continued efforts to include minorities in research and clinical trials are essential components of NIH's minority health and health disparities activities.

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GOAL 5: Support training to enhance the diversity of the biomedical workforce and to promote training and advancement of minority health and health disparities researchers

NIH's continued promotion of a skilled and diverse workforce will facilitate further advancements in the fields of minority health and health disparities research. A modern and robust workforce with diverse skill sets and core competencies unique to minority health and health disparities research is needed to address complex research questions. Programs that address MH and HD workforce preparedness at the individual level will enhance the expertise of the field and lead to improved capacity for promoting minority health and addressing health disparities. Individuals identifying as racial and ethnic minorities, individuals with less privileged SES, and individuals with disabilities are often underrepresented in the biomedical research workforce. Diversity of the biomedical workforce can be improved through both individual-level programs and institutional infrastructure aimed at increasing domestic and international opportunities for individuals from health disparity populations, including underrepresented groups, to pursue scientific careers. A diverse biomedical workforce also ensures an assortment of ideas, perspectives, and backgrounds among the researchers and scientists contributing to breakthroughs in biomedical research.

STRATEGY 5.1: Support individual-level programs to train individuals from health disparity populations in the biomedical sciences.

ACTION PRIORITY AREAS

Starting Line:

- Link interested students and early-career scientists from diverse backgrounds, including underrepresented groups, to researchers across various research disciplines, both at NIH and in the extramural research community. NIH encourages these links to be established from pre-college or university stages through junior faculty stages to enhance the biomedical research training pipeline.
- Enable individuals from diverse backgrounds, including underrepresented groups, to achieve research career independence by providing networking events, best practices, and guidance on NIH grantsmanship and the peer review processes to facilitate (1) both short- and long-term success in NIH grant application submissions and (2) achievement of tenure in a suitable timeframe and reentry into the biomedical workforce. These resources may be offered at symposia and workshops, in NIH announcements, at scientific meetings, and on training websites.

Building Momentum:

- Take steps to enhance, renew, or expand NIH's portfolio of scientific education and training opportunities for individuals from health disparity populations, including underrepresented groups, for all career stages from pre-college or university through tenure-track faculty.

STRATEGY 5.2: Support current and novel institution-level programs at institutions that have a historical and current commitment to educating underrepresented students and at less research-intensive institutions to enhance the ability of these programs to recruit, train, and retain a diverse biomedical research workforce.

ACTION PRIORITY AREAS

Starting Line:

- Support intramural NIH and extramural programs that enable institutions that have a historical and current commitment to educating underrepresented students and less research-intensive institutions to recruit, train, and retain scholars from health disparity populations, including underrepresented groups, in biomedical science across all career stages from undergraduate through junior faculty stages across various basic, clinical, and data science research domains.

Building Momentum:

- Take steps to enhance research and training environments at NIH and in the extramural research community for undergraduate, graduate, and medical institutions serving underrepresented students.

Case: 25-16 Case Document 10-07-2025 Document Page 38 Dated Filed 10/25/2025 Page 26 of 39 ID: 6756750

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STRATEGY 5.3: Promote diversity-supporting recruiting programs at research-intensive institutions to expand the pool of applicants from health disparity groups underrepresented in biomedical research.

ACTION PRIORITY AREAS

Starting Line:

- Support recruiting efforts to interest individuals from underrepresented backgrounds to apply for opportunities to access and make contributions to NIH-supported research projects in research-intensive institutions. These opportunities will help them develop the essential skills and knowledge required to achieve their next level of career goals.

Building Momentum:

- Take steps to enhance diversity and inclusion efforts at research-intensive institutions to provide a more welcoming environment for prospective researchers from underrepresented backgrounds from pre-college or university stages through junior faculty stages.

STRATEGY 5.4: Support training and mentorship programs for minority health and health disparities researchers at all stages of career development and leadership development.

ACTION PRIORITY AREAS

Starting Line:

- Support programs to train and mentor researchers with expertise in minority health and health disparities from pre-college or university through early-stage investigator career stages.

Building Momentum:

- Take steps to enhance, renew, or expand NIH's portfolio of scientific education, training, and mentoring opportunities for minority health and health disparity researchers from pre-college or university stages through established senior investigator careers.

STRATEGY 5.5: Incorporate development of specialized research skills into health disparities training programs, including core and emerging skills that are important for measuring, understanding, and addressing minority health and health disparities complexities.

ACTION PRIORITY AREAS

Starting Line:

- Support programs to provide researchers opportunities to enhance existing research capabilities or to acquire new research capabilities in MH- and HD-related science at the graduate student, junior scientist, and senior scientist levels of career stages.

Building Momentum:

- Take steps to enhance, renew, or add to NIH's portfolio of intramural and extramural programs dedicated to the development of specialized research skills into minority health and health disparities research programs, including those fostering the development of scientists from medical, dental, veterinary, and other health science disciplines.

GOAL 6: Strengthen the national capacity to conduct minority health and health disparities research

This goal promotes the expansion of the national capacity to conduct minority health and health disparities research. Creating and/or enhancing infrastructure to support novel and existing research approaches will facilitate further advancements in the fields of minority health and health disparities. Programs that address workforce preparedness at the institutional level will strengthen the capability of the fields to conduct novel and applied research.

Case: 25-16 Case Document 10707-B350955 Document Page: 38316 Date Filed: 04/25/2025 Page: 27 of 39 ID: 6756750

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STRATEGY 6.1: Support programs to enhance capacity for minority health and health disparities research at all institutions.

ACTION PRIORITY AREAS

Starting Line:

- Support relevant investigator-initiated research projects and multidisciplinary research centers in less research-intensive academic institutions—such as institutions that have a historical and current commitment to educating underrepresented students and primarily undergraduate institutions—that train significant numbers of individuals from health disparity populations.
- Support multidisciplinary centers and networks with local, regional, national, and international shared research resources such as databases, informatics cores, and biospecimen repositories that have meaningful inclusion to foster collaborative translational research relevant to U.S. health disparity populations.
- Build research capacity in community-based and tribal organizations that are positioned to conduct population health research on understudied racial and ethnic minority populations because of their trusted relationships with those populations.
- Support annual meetings, symposia, and research education programs across the United States to foster the development of a diverse cadre of faculty, students, and community partners who are committed to pursuing research on minority health and health disparities.

Building Momentum:

- Build community-based research hubs that serve as resource centers in order to foster collaborative, community-engaged research to address minority health and health disparities.
- Accelerate efforts to advance understanding of links between environmental exposures and health outcomes to promote environmental health literacy and support disease prevention efforts targeted to entire communities or regions at risk.
- Develop innovative ways to sustain community-based environmental health disparities research beyond individual grant cycles, and provide the means for community partners and citizen scientists to be more actively engaged with research.

STRATEGY 6.2: Develop and test methods to foster, coordinate, and promote the field of health disparities among research institutions and organizations.

ACTION PRIORITY AREAS

Starting Line:

- Disseminate the NIMHD Health Disparities Research Framework to inform and attract researchers from various scientific disciplines to explore the interplay between biological, behavioral, social, cultural, environmental, and clinical determinants of health.

Building Momentum:

- Partner with organizations that certify/license community health workers (CHWs) to standardize training of CHWs in intervention research, and assess the impact on health disparity intervention research, efficiency, safety, scientific rigor, and reproducibility.
- Expand NIH efforts to advance citizen science in the field of health disparities as a distinct research enterprise led by citizen scientists and community organizations, going beyond traditional approaches to community-engaged research led by academic institutions.

GOAL 7: Ensure appropriate representation of minority and other health disparity populations in NIH-funded research

This goal promotes the inclusion of individuals from minority and other health disparity populations (e.g., SGMs, rural, less privileged SES) in all federally funded research with human participation. Promoting inclusion in research requires attention throughout the research process, encompassing study design, implementation, and analyses. Using evidence-based strategies for

Case: 25-16 Case Document 10-07-2025 Document: 38-2 Page: 3406 Date Filed: 10/25/2025 Page: 285 of 339 ID: 6756750

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outreach within minority communities and study design to enable subpopulation analyses, researchers can promote higher levels of representation among minority groups and SGMs to understand whether clinical advances are equally effective among all population groups. Appropriate inclusion of minorities may also support more meaningful insight into the etiology of minority health concerns and could inform more effective, culturally competent interventions in minority populations.

STRATEGY 7.1: Provide guidance, recommendations, and technical assistance for NIH-funded researchers in appropriate study design and best practices for recruitment to ensure compliance with laws, regulations, and policies regarding the inclusion of minorities and other health disparity populations in research.

ACTION PRIORITY AREAS

Starting Line:

- Support the development of technical assistance and best-research-practice centers to ensure that researchers have knowledge of proper study design and recruitment practices for including underrepresented health disparity populations in research.

Building Momentum:

- Develop general guidance for NIH researchers on how to best incorporate and include underrepresented health disparity populations in research.
- Expand local, regional, and national efforts to assess the impact of policies and policy changes on minority population health, and delineate specific mechanisms by which policies or policy changes mitigate or exacerbate systemic social, economic, and environmental disadvantages.

STRATEGY 7.2: Promote tracking of originally proposed recruitment strategies and objectives to ensure sufficient samples for analyses of subpopulation data.

ACTION PRIORITY AREAS

Starting Line:

- Educate and provide support to research centers regarding optimal recruitment strategies for inclusion of underrepresented health disparity populations in research.

Building Momentum:

- Develop Requests for Information (RFIs) to generate recommendations for improved tracking of recruitment strategies and objectives to ensure sufficient sample sizes for analyses of health disparity populations and related subpopulation data.

STRATEGY 7.3: Promote inclusion of minorities and other health disparity populations in big data sets, clinical research, and future big science initiatives.

ACTION PRIORITY AREAS

Starting Line:

- Support established and new research centers in the engagement of underserved health disparity communities for recruitment and retention in big data science research.

Building Momentum:

- Develop systematic monitoring mechanisms to assess successful recruitment and retention of health disparity populations in NIH-supported research.
- Strengthen national efforts to increase representation of health disparity populations in disease registries and public health surveillance systems to improve understanding and awareness of population health differences within and between groups and across geographic regions.

Case: 25-16 Case 1:25-cv-10787-BEM Document: 38-16 Filed: 04/25/2025 Page: 295 of 391 ID: 6756750

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DETAILS OF CATEGORIES AND GOALS

OUTREACH, COLLABORATION, AND DISSEMINATION: GOALS AND STRATEGIES

Outreach, collaboration, and dissemination efforts enable the communication of key findings of minority health and health disparities research to be shared with the people and communities that need them. These activities help advance the development of dissemination plans to enhance networks of minority health and health disparities researchers and stakeholders across the nation and within NIH.

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GOAL 8: Promote evidence-based community engagement, dissemination, and implementation of minority health and health disparities research best practices

This goal advances evidence-based community outreach and dissemination, and implementation of findings from minority health and health disparities research into clinical, community, and everyday settings. Dissemination and implementation strategies should be embedded as core components of the research process from the initial stages. Developing and testing strategies for dissemination and implementation of scientific advances will facilitate the translation of research into policy and practice.

STRATEGY 8.1: Develop and test best practices for dissemination and implementation of minority health and health disparities research discoveries into different settings and with different populations.

ACTION PRIORITY AREAS

Starting Line:

- Test best practices for dissemination and implementation of minority health and health disparities research discoveries in diverse diseases and conditions into rural communities, communities with a high proportion of populations with limited English proficiency, and communities with a high proportion of populations with low health literacy.

Building Momentum:

- Develop and test an agency-wide Language Access Plan (LAP) to improve access to health communication modalities, such as online and/or written materials, for dissemination and implementation of minority health and health disparities research discoveries for conditions in rural communities, communities where English is not the primary language, and communities with low health literacy.

STRATEGY 8.2: Conduct studies to determine strategies for effective population-specific communication and outreach to inform recruitment and retention into clinical research studies and databases, design of culturally appropriate health interventions, and community engagement and participation in research.

ACTION PRIORITY AREAS

Starting Line:

- Disseminate culturally appropriate educational materials and evidence-based interventions to appropriate communities to increase participation in research studies and clinical trials amongst health disparity populations.

Building Momentum:

- Design and conduct educational interventions to engage underserved communities and encourage participation in health disparity research and evaluate the effects of culturally appropriate outreach strategies related to basic, behavioral, clinical, and genomic research participation.

STRATEGY 8.3: Generate strategies and tools to transform minority health and health disparities best practices into policies.

ACTION PRIORITY AREAS

Starting Line:

- Assess outreach tools and strategies that address minority health and health disparity concerns, including risk and prevention, to determine best evidence-based practices to be implemented and promoted into policies for care.

Building Momentum:

- Enhance targeted efforts that result in shorter lag time between collecting evidence and adopting evidence-based efforts in dissemination/implementation that drive policy decisions.

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- Ensure that culturally appropriate strategies and tools are properly disseminated and implemented in relevant populations, in an effort to influence policy with successful evidence-based methods.
- Establish working relationships with policy think tank organizations to inform policymakers on successful minority health and health disparity practices that should be disseminated and implemented on a larger scale.

GOAL 9: Cultivate and expand a community of minority health and health disparities researchers and advocates

This goal promotes a community of minority health and health disparities–focused research within NIH, HHS, and beyond. The community should include NIH, other government agencies, academia, and the private sector. Through collaboration and partnerships, the community should advance the sciences of minority health and health disparities as well as integrate supporting structures and activities, such as quarterly or biannual science highlights and discussions at major NIH meetings. The development of this community also may help to ensure that MH and HD research questions are integrated into mainstream, disease-focused scientific communities and ensure that the impact of health disparities is considered across disciplines.

STRATEGY 9.1: Build an NIH-wide interdisciplinary community of scholars around minority health and health disparities research to coordinate disparities science and to foster accountability and integration of minority health and health disparities science within NIH research activities.

ACTION PRIORITY AREAS

Starting Line:

- Promote intramural training opportunities that support minority health and health disparities science, such that projects are designed with enough power for subpopulation or granular analysis in conjunction with primary analyses.
- Promote extramural training opportunities that support minority health and health disparities science, such that projects are designed with enough power for subpopulation or granular analysis in conjunction with primary analyses.

Building Momentum:

- Ensure the dissemination and diffusion of health disparity research activities and results to diverse groups within NIH.
- Create an annual event at NIH to showcase health disparities science with regard for the health determinants and integration into biomedical research.

STRATEGY 9.2: Promote interagency collaboration and coordination with federal departments and agencies, including use of common data elements and data sharing relevant to health disparities research.

ACTION PRIORITY AREAS

Starting Line:

- Improve the generalizability of health disparity research findings by coordinating with other federal agencies in the development and administration of population surveys that use common data elements.
- Improve health literacy by working with sister agencies to develop and disseminate research-based educational information to specific health disparity communities.

Building Momentum:

- Provide research results to working groups for the Healthy People 2030 initiative and similar federal initiatives to facilitate health disparity data sharing for decisionmaking.

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STRATEGY 9.3: Establish partnerships with nongovernmental groups, such as mentoring networks, foundations, professional organizations, advocacy groups, industry, science communities, and grantees, to advance the development, improvement, and utilization of minority health and health disparities definitions, methods, measures, metrics, interventions, and best practices.

ACTION PRIORITY AREAS

Starting Line:

- Disseminate NIH health disparity research priorities and research results through lecture series and workshops to a variety of audiences, including current and potential health disparities researchers.
- Generate interest in NIH health disparity research priorities and research results through onsite activities at NIH campuses to diverse populations of secondary school and undergraduate students.
- Improve health literacy through nationwide initiatives that increase the public's access to science-based information about specific health disparity illnesses and conditions.

Building Momentum:

- Improve health literacy through nationwide initiatives that increase the public's access to science-based information about specific illnesses and conditions in culturally appropriate formats that influence minority health.
- Provide overall coordination of community groups to identify minority health and health disparities research priorities for specific illnesses or conditions to disseminate relevant findings and/or foster additional research venues.

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LEAP FORWARD RESEARCH CHALLENGE

Leap Forward priority areas represent visionary science that aims to reshape the sciences of minority health and health disparities. These leaps present bold progressive actions to improve minority health and to reduce health disparities across relevant diseases, disorders, and conditions.

Case: 25-16 Case Document 10-07-2025 Docu Page 38 46 Dated 04/25/2025 Page 34 of 39 ID: 6756750

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The Leap Forward priority areas represent one way the ICs will comply with the 21st Century Cures Act, as described in Section 2031 of P.L. 114–255, to promote collaborations of research projects across all NIH ICs and Offices focused on reducing and/or eliminating health disparities.

Minority Health and Health Disparities Research

- Promote research that reduces new HIV infections by 75 percent by 2030, especially in African American or Black, Hispanic or Latino, and SGM populations, which are disproportionately affected by HIV.
- Promote research that increases viral suppression to 85 percent of persons with HIV from health disparity populations, especially African American or Black and Hispanic or Latino men who have sex with men and other SGM populations, by 2030.
- Promote research that increases pharmacological curative treatment of hepatitis C infection among American Indian and Alaska Natives by 50 percent by 2030.
- Foster research that uncovers contributors and develops interventions to reduce maternal mortality and severe maternal morbidity in the United States over the next 10 years in order to address the disparities between African American or Black and American Indian and Alaska Native women compared with White women.
- Reduce racial and ethnic, socioeconomic, and/or geographic disparities in pre-term birth and infant mortality over the next 10 years.
- Implement measures to increase diverse ancestral representation from African Americans or Blacks, Hispanics or Latinos, American Indians, Alaska Natives, and Pacific Islander populations in NIH-supported and analyzed genomic data sets, in order to approach proportional representation of the U.S. population by 2030.
- Increase rates of colorectal cancer screening, follow-up, and referral to care among racial and ethnic minority populations, persons of less privileged SES, SGM populations, and underserved rural populations, to attain targeted national standards by 2030.
- Increase access to medications for opioid use disorder among those incarcerated or recently released so that 75 percent of persons in all racial and ethnic subpopulations of the incarcerated or recently released persons are linked with such care by 2030.
- Improve understanding of incidence patterns, symptoms, diagnosis, and disease trajectories for vascular cognitive impairment and dementia in racial and ethnic minority populations by 2030.
- Bring curative genetic therapies for sickle cell disease (SCD) into first-in-human clinical trials within five years and increase the proportion of Medicaid and Medicare beneficiaries with SCD who receive disease-modifying therapies.
- Support community-engaged, community-based implementation research to reduce cardiovascular health disparities, sustain adoption of evidence-based interventions, mitigate disparities in adoption of health behaviors, and promote enhanced characterization of social determinants of health to improve cardiovascular health and disease prevention across the lifespan and maximize impact on overall population health in five high-burden communities by 2030.
- Build on global experiences to dramatically transform health care and clinical outcomes in rural and socioeconomically disadvantaged populations in the United States by engaging 25 percent of the training programs in certified biomedical engineering departments in the United States (approximately 30) by 2030, to drive the development of recognized and active health care disparities technology development.
- Support research to test at least three multilevel approaches to improve adoption of evidence-based asthma interventions in African American or Black, Hispanic or Latino (e.g., Puerto Rican), and socioeconomically disadvantaged communities with the goal of reducing asthma-specific emergency room visits, hospitalizations, and symptom days in these populations by 2030.

Case: 25-16 Case Document 10-1 Filed 04/25/25 Page 38 of 39 Page ID: 6756750

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- Support development of one synthetic or hybrid data set which conforms to FAIR (findable, accessible, interoperable, and reusable) open data principles and models racially and ethnically diverse communities in order to test methods and metrics and address possible biases due to underrepresentation of minorities and women within the next 10 years.
- Define the rates of hearing impairment by race and ethnicity by 2030.
- Support research that advances implementation of evidence-based interventions and tools for reducing untreated dental decay in racial and ethnic minority and low-income populations across the lifespan by 10 percent to 25 percent by 2030, with the long-term potential for improved health for all communities.
- Identify differences in factors that cause progression to end-stage renal disease (ESRD) and find informative subpopulations among African Americans or Blacks, Hispanics or Latinos, American Indians, Alaska Natives, Pacific Islanders, and Asians with chronic kidney disease by 2030.
- Identify factors contributing to the disparity between Whites and African Americans or Blacks, Hispanics or Latinos, American Indian, Alaska Natives, Pacific Islanders, and Asians in control of HbA1c (glycated hemoglobin), and target those factors through rigorous clinical trials and adaptive population-based interventions by 2030.
- Address the leading causes of morbidity and mortality in NIH-designated health disparity populations by 2030 by leveraging the network of Clinical and Translational Science Awards (CTSA) Program to (1) develop research into underlying factors related to clinical trial design and conduct to improve outcomes and/or reduce disparities, (2) demonstrate the effectiveness of delivering treatments that consider the health care context of a given minority or health disparity population(s), and (3) assess strategies for the pragmatic dissemination and uptake of these interventions into routine health care settings by 2030.
- Identify mechanisms that account for marked differences in suicide rates across racial and ethnic groups and SGM populations, as well as develop and test strategies to improve suicide risk prevention and detection among population groups at risk within the next 10 years.
- Develop and test innovative approaches to remediate barriers that contribute to documented inequities in access, engagement, and quality of mental health treatment and services, and/or the effectiveness and outcomes of evidence-based mental health interventions for health disparity populations by 2030.
- Understand the underlying etiologic pathways for the higher rates of systemic lupus among African American women and Latinas compared to White women by 2030.
- Assess the efficacy of interventions to reduce disparities between racial and ethnic minority populations and Whites in access to and use of existing surgical and nonsurgical interventions for osteoarthritis by 2030.
- Characterize and understand how adverse environmental exposure profiles that occur during early life stages may enhance vulnerability to diseases of adulthood disproportionately in health disparity populations.
- Understand the acute and long-term health impacts of natural and human-made disasters on less privileged SES and minority populations and the health care systems serving them. In addition, understand the individual, community, and health care system response prevention factors to improve the acute and long-term health, well-being, and resiliency of those affected.
- Assess differences and similarities in wellness and disease prevention behaviors given the intersectionality of race and ethnicity, geographic area, SGM populations, and SES by 2030.
- Understand the underlying etiologic pathways that help explain the higher rates of glaucoma among African Americans or Blacks compared with Whites by 2030.

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- Within the next 5 years, synthesize the latest evidence regarding the **immigrant paradox** in health outcomes to better define protective factors, such as resilience or social support; differentiate the protective factor profiles of various immigrant groups; and/or determine the extent to which methodological, measurement, or sampling artifacts explain the paradox.
- By the year 2030, conduct research to examine the impact of laws, policies, and structural determinants of health on defined health disparities with emphasis on non-health societal sectors, such as transportation, housing, communications, water and energy providers, agriculture, land use, public safety, education, and criminal justice.
- Support research to document and understand occupational health disparities as determined by the type of employment and work conditions (e.g., safety, work shifts, paid leave, health insurance) controlling for race and ethnicity, SGM populations, SES, and geographic residence by 2030.
- Over the next 5 years, support research to examine the effectiveness, financing, and sustainability of programs using community health workers, patient care coordinators, and other peers to deliver prevention and self-management interventions to reduce disparities.
- By the year 2030, support research to achieve health equity in the use of recommended preventive services that target three leading causes of death in the United States—cancer, heart disease, and diabetes—through culturally derived and community-engaged interventions that include multiple clinical and community settings.
- Promote research examining the role of the built environment and its interactions with multiple individual behavioral, biological, and cultural factors as well as health care systems that promote health equity in screening, early diagnosis, treatment and self-management, and prevention of complications of chronic diseases in the clinical setting across the next 5 years.
- Support experimental research using simulations to understand potential bias in peer review of minority health and health disparity-related applications due to characteristics of applications or of reviewers by 2030.
- Identify evidence-based interventions to prevent and reduce alcohol misuse, including underage and excessive alcohol use, among health disparity populations.
- Over the next five years, support research that examines health information technology and its impact on minority health and health disparity populations access to care, quality of care, and overall health outcomes.

Research-Sustaining Goals

- Increase the overall proportion of participants from diverse populations included in NIH-funded clinical research to 40 percent by 2030 and within specific major disease categories.
- Increase the diversity of institutions conducting genomic research and training by investing in faculty at such institutions, along with curriculum-building partnerships, to accelerate workforce development in underrepresented and under-resourced communities within the next 10 years.
- By 2030, promote research collaborations between U.S. and Latin American scientists addressing prevention of childhood obesity and diabetes in U.S. Latinos and in Latin America.
- Increase training opportunities for students from health disparity populations, including underrepresented groups, to learn about health equity and biomedical research in low- and middle-income countries.
- Increase our understanding of cancer trends and outcomes in the context of disparities and subpopulations through the expansion of the Surveillance, Epidemiology, and End Results program to include 50 percent of the population by 2030.
- Increase the number of underrepresented biomedical scientists as defined by the National Science Foundation from current levels by 25 percent by 2030.

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- Cultivate a cadre of biomedical and behavioral investigators trained in implementation research who are fully prepared to bridge NIH mission areas in both clinical and nonclinical, real-world settings by increasing (a) the number of investigators overall and (b) the number of investigators from underrepresented backgrounds with requisite skills by 25 percent by 2030.
- Develop a toolbox of consensus common data elements (CDEs) on sociodemographic characteristics, population descriptors, and social determinants of health, and require use of CDEs in future Funding Opportunity Announcements (FOAs) by 2030.
- Develop a new program to enable investigators who have participated in diversity-enhancing programs sponsored by NIH to recognize and apply for continuing educational opportunities, such as the Ruth L. Kirschstein National Research Service Award (NRSA) and institutional training awards for predoctoral or postdoctoral training positions, K99-R00, and other training grant opportunities.
- Support individual-level programs to train individuals from health disparity populations, including those that are underrepresented in the biomedical sciences

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FUTURE PLANS

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Implementation Plan

Progress will be monitored annually by tracking NIH's progress toward the set goals and the targets under Starting Line and Building Momentum. This process will assess progress, monitor budgets, and provide feedback to NIH on the implementation process (see Figure 2).

- Promote the implementation of goals, strategies, and priorities.
- Create a system to track and monitor progress toward achieving the goals, strategies, and priorities.

Evaluation Plan

- Evaluate strategic plan through qualitative and quantitative metrics without overly prescriptive endpoints.
- Measure utility of strategic plan to multiple stakeholders.
- Measure impact by co-sponsored Funding Opportunity Announcements (FOAs, changes in portfolio, project self-evaluations, and others.
- Gap analysis based on NIH's ICs responses to priority area requests.

FIGURE 2: Strategic Plan Monitoring and Tracking

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Date Filed: 05/19/2025 Page 2 of 8 Entry ID: 6756750

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Contracts

What is a Contract?

A contract is a legal agreement binding parties that has:

- Defined requirements
- Specific deliverables
- Defined schedule

A contract may be cost or price based.

Grants vs. Contracts

Grant	Contract
• Assistance	• Legally binding agreemen

↑ Back to Top

A1499

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Date Filed: 05/19/2025 Page 3 of 8 Entry ID: 6756750

Grant	Contract
mechanism to support research for the public good • Peer review of broad criteria • Limited government oversight and control • Reports	acquire goods or services for the direct use or benefit of the government. • Award based on stated evaluation factors • More government oversight and control • Deliverables

Finding a Contract Solicitation

All contract solicitations are posted on the Contract Opportunities page in Sam.gov. This site serves as the fed-wide portal that supports searching, monitoring, and retrieving contract opportunities for the federal government.

Or you can search for NIH specific opportunities in the NIH Request for Proposal Directory by the NIH institute or center of interest.

Types of Contracts

Fixed Price

- Firm price for delivery of a product or service
- May result from sealed bids or negotiations
- Most often for supplies and standard services

Cost Reimbursement

- Contract contains a negotiated estimate
- May or may not have a fixed fee
- Used when
  - Uncertainties involved in contract performance do not permit costs to be estimated with sufficient accuracy use any type of fixed-price contract

↑ Back to Top

A1500

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Date Filed: 05/19/2025 Page 4 of 8 Entry ID: 6756750

- Used when costs cannot be estimated with sufficient accuracy to use any type of fixed-price contract
- Most Research and Development (R&D) contracts are cost-reimbursement

How Contracts Are Evaluated

- Contract awards from proposals are usually made on the basis of best value.
- Evaluation factors for award
  - Technical criteria
  - Cost
  - Past performance
  - Small disadvantaged business participation
- Best value considers all factors based on the relative importance
- Technical evaluation criteria are reviewed by independent peer review
  - Sample technical evaluation criteria
    - Technical approach
    - Personnel
    - Facilities
- Technical criteria are often weighted
- Reviewers determine technical acceptability

Submitting a Contract Proposal

Search for a contract opportunity on Contract Opportunities page in Sam.gov or NIH Request for Proposal Directory.

Read the solicitation carefully! It should contain all the information needed to prepare a proposal.

- Registration requirements
- Statement of Work (SOW) or Statement of Objectives (SOO)
- Instructions to offerors

↑ Back to Top

A1501

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Filed 05/19/25 Page 5 of 8 Entry ID: 6756750

- Type of contract
- Set- aside restrictions
- How and where to submit the proposal

- Evaluation factors for award

When Developing a Proposal

1. Convince reviewers of your technical abilities!
   - Demonstrate your understanding of the requirement
   - Demonstrate the soundness of your technical approach
   - Show the strengths of your technical team
   - Present facilities
   - See Technical Proposal Instructions
2. Ensure your proposal is cost competitive
   - See Business Cost Proposal Instructions

Review Criteria

To find the criteria reviewers will use to evaluate your application, see Section V of your funding opportunity.

See Also

Contract Regulations

Policies and procedures for acquisition by all executive agencies are codified in the Federal Acquisition Regulations (FAR).

Contact

These Acquisition Offices service the NIH Institutes and Centers.

↑ Back to Top

A1502

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Filed 05/19/25 Page 6 of 8 Entry ID: 6756750

This page last updated on: September 13, 2024
For technical issues E-mail OER Webmaster

Thank you for taking the survey. We will use this information to continue to improve your experience on our site.

Form Approved OMB# 0925-0648 Exp. Date 7/2027

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↑ Back to Top

A1503

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Date Filed: 05/19/2025 Page 7 of 8 Entry ID: 6756750

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Archive of this Page Since September 24, 2024

Older Versions of this Website

Site Map

↑ Back to Top

A1504

Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-1 Filed 05/19/25 Page 8 of 8 Entry ID: 6756750

Home

New To NIH

Funding

Grants Process

Policy & Compliance

News & Events

About Us

↑ Back to Top

A1505

March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicant organizations should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the (//grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grant (Parent T35)

Activity Code

T35 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t35&Search.x=0&Search.y=0&Search_Type=Activity) National Research Service Award (NRSA) Short-Term Research Training

Announcement Type

Reissue of PA-23-080 (https://grants.nih.gov/grants/guide/pa-files/PA-23-080.html)

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=42231) associated with this funding opportunity

- **March 31, 2025** - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).

Funding Opportunity Number (FON)

PA-25-280

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.351, 93.866, 93.173, 93.867, 93.213, 93.273, 93.286, 93.847, 93.233, 93.113

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students interested in careers within biomedical, behavioral, or clinical research workforce. Many NIH Institutes and Centers (ICs) use this NRSA program exclusively to support intensive, short-term research training experiences for health professional students (medical students, veterinary students, and/or students in other health-professional programs) during the summer. This program is also intended to encourage training of graduate students in the physical or quantitative sciences to pursue interests in careers within the biomedical research workforce by providing short-term exposure to, and involvement in, the health-related sciences. The training should be of sufficient depth to enable the trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Funding Opportunity Goal(s)

NIH's 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..

Key Dates

Posted Date

January 03, 2025

Open Date (Earliest Submission Date)

December 25, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH standard due dates (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	August 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	August 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	August 2027	December 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	May 07, 2028 *	July 2028	August 2028	December 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicant organizations are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

May 08, 2028

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicant organizations must read and follow all application instructions in the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply

Case: 25-1610 Case: 1:25-cv-01871 Document: 00118068954 Document: 172-5 Filed: 05/19/2025 Page: 5 of 24 Case ID: 6756750

Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-280) Workspace to prepare and submit your application and eRA Commons (http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 1. Overview Information
- Key Dates

Part 2. Full Text of Announcement
- Section I. Funding Opportunity Description
- Section II. Award Information
- Other Award Budget Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall purpose of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//grants.nih.gov/grants/guide/url_redirect.php?id=41125) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical and professional skills development appropriate for the appointed trainees that provides added value to already existing programs.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The goal of the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (T35) program is to develop and/or enhance research training opportunities for health professional students and for graduate students in the physical or quantitative sciences interested in careers in biomedical, behavioral and clinical research workforce that are relevant to the NIH mission. The T35 program provides short-term support for a period of at least 8, but no more than 12, weeks in a grant year for full-time training experiences under the supervision of experienced researchers. Trainees are exposed to mentors with active research careers and learn about further research training opportunities and research career options. The training program should be of sufficient depth to enable selected trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but the proposed program must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

Institutional short-term training grants are intended to introduce predoctoral students to research that would not otherwise be available through their regular course of graduate study. The research experiences should be tailored to the individual to meet their training goals. Didactic instruction must

include training in the responsible conduct of research. Positions on NRSA short-term institutional training grants may not be used for courses and study leading to the MD, DDS, DO, DVM, or other clinical, health professional degree, nor to support residency training.

Research elective credit may be granted for students who complete a short-term, research training experience supported by the T35. The decision to award elective credit will be at the discretion of the sponsoring institution and must be consistent with the policies of the institution (see Funding Restrictions).

Recipient organizations may provide training to students enrolled at other institutions through a partnership or consortium structure. Consortia should be well justified to enhance the goals and objectives of the training program. Consortium partners will be identified by the applicant organization, and each partner institution must identify faculty at their location who have agreed to serve as mentors.

Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicant organizations and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.
This Notice of Funding Opportunity (NOFO) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicant organizations **MUST** consult the **Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)**, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal
Resubmission
Revision

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement - Institutional Research Training Grants* (//grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T35 short-term institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicant organizations are encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicant Organizations

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

Case: 25-1610 Case: 1:25-cv-01807-JPH-MKK Document: 12-5 Filed: 05/19/2025 Pages: 8 Entry ID: 6756750

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), (//grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicant organizations should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) (https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) – Applicant organizations must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicant organizations must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program consistent with applicable law, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports

as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program.When building a training team, programs should include faculty who are committed to training, mentoring, and providing safe and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

Case: 25-1611 Case: 25-1611 Document: 10-2 Page: 95 Document: 7275 Filed: 05/19/2025 Page: 95 Filed: 05/19/2025 10 Ed 21 ID: 6756750

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term faculty), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- Faculty, Trainees, and Training Record
- Other Training Program
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicant organizations to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Particular attention must be given to the required International **Training Data Tables** (//grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applicant organizations should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective trainee candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique background and skill set that will enhance training. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicant organizations should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

- The efforts made to recruit a pool of prospective program faculty from a range of career stages and scientific disciplines relevant to the training goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of all trainees. Include the planned format, duration, and frequency of mentor training activities for program faculty and a description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples of relevant topics include, but are not limited to:
    - Aligning expectations.
    - Maintaining effective communication.
    - Fostering independence.
    - Assessing scholars' understanding of scientific research.
    - Enhancing professional development.
    - Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, and professional development, and how these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicant organizations and trainees will be provided with information about the overall biomedical research workforce employment landscape, the variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.
- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Training Program Evaluation

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is safe and supportive of trainee development.

Case: 25-1611 Case: 25-1611 Document: 00118076995 Document: 7295 Filed: 05/19/2025 Page: 12 Filed: 05/19/2025 Page: 12 Fil ID: 6756750

- The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the Training Data Tables (https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of all trainees within the program (i.e., retention). Applicant organizations are encouraged to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

Institutional Environment and Commitment to Training

- The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing a safe and supportive environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://grants.nih.gov/grants/forms/data-tables.htm) . The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5 (https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree Training Table 8 (https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8). (https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote safe and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting a safe and supportive scientific environment.
- Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting safe and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4 (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm) regarding NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality research); ensuring the research facilities are accessible to trainees with disabilities.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-22-129 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-129.html)).
- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicant organizations are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicant organizations must then complete the submission process by tracking the status of the application in the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicant organizations are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies

(//grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicant organizations must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form.Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide (https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35 (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicant organizations are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.php?id=82299).

Any instructions provided here are in addition to the instructions in the policy.

Substitute the term "scholars" for all references to "trainees" in the SF424 (R&R) Application Guide, and substitute the term "career development" for all references to "training" in the SF424 (R&R) Application Guide.

Section V. Application Review Information

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 (//grants.nih.gov/grants/guide/url_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex of trainee candidates, trainees, or faculty may not be used as factors in the evaluation of applications.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed.)

Case: 25-1611 Case: 25-1611 Document: 00118167095 Document: 7225 Filed: 05/19/2025 Pages: 15 Filed: 05/19/2025 Entry ID: 6756750

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major biomedical research training impact.

Training Program and Environment

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers?
- Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

- Does the application provide a compelling rationale for the proposed short-term research training program and include appropriate training goals and objectives relevant to the rationale? Are the objectives, design, direction, and quality of the proposed short-term research training program likely to ensure effective training?
- Are the proposed courses, structured training activities, mentoring, and research experiences - where applicable - appropriate for the level of trainees and the area(s) of science to be supported by the program? Do the program activities appropriately introduce trainees to transparent, rigorous, and reproducible research methodologies?
- If appropriate, does the program provide training in inter- or multi-disciplinary research and/or provide training in state-of-the-art or novel methodologies and techniques?
    - Is the proposed program of training likely to ensure that trainees will acquire knowledge and skills necessary to prepare them for a research career? Does the program include features likely to encourage short-term trainees to consider careers in health-related research?
- Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee success?
- **For applications designating multiple PDs/PIs:**
    - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
    - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/PIs?

Preceptors/Mentors

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of all trainees?
- Do participating faculty appropriately promote the trainees' career progression?

- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

Trainees

- Does the proposed short-term training program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training goals and objectives? Are the outlined recruitment strategies likely to identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?

- Does the program have access to and the ability to recruit high quality, short-term trainees from the applicant institution or another health-professional school?
- Are the recruiting procedures and trainee selection criteria appropriate and well defined?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?

Training Record

- How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?
- **For applications that request short-term research training positions,** is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) ***Subject Matter –*** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) ***Faculty Participation -*** Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) ***Duration of Instruction -*** Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) ***Frequency of Instruction –*** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

Case: 25-1611 Case: 25-1611 Document: 00118107318 Document: 00118107318 Page: 95 Page: 95 Date Filed: 05/19/2025 Date Filed: 05/19/2025 Entry ID: 6756750

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the short-term training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the short-term research training experience during the next project period?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

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.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by {LOCUS OF REVIEW} in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications 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 an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- 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.

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 Section 2.5.1. Just-in-Time Procedures. (//grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

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.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://grants.nih.gov/grants/pre-award-process.htm#award)

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
    - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-_suspension__termination__and_withholding_of_support.htm).

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it (https://www.healthit.gov/topic/certification-ehrs/certification-health-it) to learn more.

Case: 25-1611 Case: 25-1611 Document: 00118167095 Document: 7265 Filed: 05/19/2025 Page: 19 Filed: 05/19/2025 Page: 19 Entry ID: 6756750

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data)

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in achieving its goals, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

For programs involving undergraduate students:

- Successful completion of an undergraduate degree in a STEM field
- Pending application for and/or enrollment in an advanced degree program in a STEM field
- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field

For programs involving graduate students:

- Successful completion of a STEM graduate program
- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

For programs involving postdoctorates and early career investigators:

- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the **Table of IC-Specific Information, Requirements, and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

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NEI - NATIONAL EYE INSTITUTE
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E-mail: agarwalnee@nei.nih.gov (mailto:agarwalnee@nei.nih.gov)

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Jennifer N. Baumgartner, Ph.D.
National Center for Complementary and Integrative Health (NCCIH)
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Email: jennifer.baumgartner@nih.gov (mailto:jennifer.baumgartner@nih.gov)

Carol Shreffler, PhD
NIEHS - National Institute of Environmental Health Sciences
Phone: 984-287-3322
Email: Shreffl1@niehs.nih.gov (mailto:Shreffl1@niehs.nih.gov)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Karen Robinson Smith
NEI - NATIONAL EYE INSTITUTE
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Jenny Greer
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Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?01-03-25)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(https://www.hhs.gov/) Department of Health and Human Services (HHS)

USA.gov (https://www.usa.gov/)

NIH... Turning Discovery Into Health®

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (https://web.archive.org/web/20250122105054/http://www.nih.gov/))

Components of Participating Organizations

Office of The Director, National Institutes of Health (OD (https://web.archive.org/web/20250122105054/https://www.nih.gov/institutes-nih/nih-office-director))

National Eye Institute (NEI (https://web.archive.org/web/20250122105054/https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://web.archive.org/web/20250122105054/https://www.nhlbi.nih.gov/))

National Institute on Aging (NIA (https://web.archive.org/web/20250122105054/https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://web.archive.org/web/20250122105054/https://www.niaaa.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://web.archive.org/web/20250122105054/https://www.nibib.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://web.archive.org/web/20250122105054/https://www.nidcd.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://web.archive.org/web/20250122105054/https://www.niddk.nih.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://web.archive.org/web/20250122105054/https://www.niehs.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://web.archive.org/web/20250122105054/https://nccih.nih.gov/))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicant organizations should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/parent_T32.html)https://grants.nih.g specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grant (Parent T35)

Activity Code

T35 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t35&Search.x=0&Search.y=0&Search_Type=Activity) National Research Service Award (NRSA) Short-Term Research Training

Announcement Type

Reissue of PA-23-080 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/pa-files/PA-23-080.html)

Related Notices

See Notices of Special Interest (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=42231) associated with this funding opportunity

- **April 4, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html).

Funding Opportunity Number (FON)

PA-25-280

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)	93.351, 93.866, 93.173, 93.367, 93.213, 93.273, 93.286, 93.847, 93.233, 93.113
Funding Opportunity Purpose	The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students interested in careers within biomedical, behavioral, or clinical research workforce. Many NIH Institutes and Centers (ICs) use this NRSA program exclusively to support intensive, short-term research training experiences for health professional students (medical students, veterinary students, and/or students in other health-professional programs) during the summer. This program is also intended to encourage training of graduate students in the physical or quantitative sciences to pursue interests in careers within the biomedical research workforce by providing short-term exposure to, and involvement in, the health-related sciences. The training should be of sufficient depth to enable the trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research. This Notice of Funding Opportunity (NOFO) does not allow Trainees to lead an independent clinical trial, but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.
Funding Opportunity Goal(s)	NIH's 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..

Key Dates

Posted Date	January 03, 2025
Open Date (Earliest Submission Date)	December 25, 2024
Letter of Intent Due Date(s)	Not Applicable

The following table includes NIH standard due dates (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	**Renewal / Resubmission / Revision (as allowed)**	**AIDS - New/Renewal/Resubmission/Revision, as allowed**	**Scientific Merit Review**	**Advisory Council Review**	**Earliest Start Date**
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	August 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	August 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	August 2027	December 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	May 07, 2028 *	July 2028	August 2028	December 2028

All applications are due by 5:00 PM local time of applicant organization.

Applicant organizations are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date	May 08, 2028
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the *NIH Guide for Grants and Contracts* (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicant organizations must read and follow all application instructions in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (https://web.archive.org/web/20250122105054/https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (/web/20250122105054/https://grants.nih.gov/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-280) Workspace to prepare and submit your application and eRA Commons (https://web.archive.org/web/20250122105054/http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 1. Overview Information
- Key Dates

Part 2. Full Text of Announcement
- Section I. Funding Opportunity Description
- Section II. Award Information
- Other Award Budget Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall purpose of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41125) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical and professional skills development appropriate for the appointed trainees that provides added value to already existing programs.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The goal of the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (T35) program is to develop and/or enhance research training opportunities for health professional students and for graduate students in the physical or quantitative sciences interested in careers in biomedical, behavioral and clinical research workforce that are relevant to the NIH mission. The T35 program provides short-term support for a period of at least 8, but no more than 12, weeks in a grant year for full-time training experiences under the supervision of experienced researchers. Trainees are exposed to mentors with active research careers and learn about further research training opportunities and research career options. The training program should be of sufficient depth to enable selected trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but the proposed program must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

Institutional short-term training grants are intended to introduce predoctoral students to research that would not otherwise be available through their regular course of graduate study. The research experiences should be tailored to the individual to meet their training goals. Didactic instruction must include training in the responsible conduct of research. Positions on NRSA short-term institutional training grants may not be used for courses and study leading to the MD, DDS, DO, DVM, or other clinical, health professional degree, nor to support residency training.

Research elective credit may be granted for students who complete a short-term, research training experience supported by the T35. The decision to award elective credit will be at the discretion of the sponsoring institution and must be consistent with the policies of the institution (see Funding Restrictions).

Recipient organizations may provide training to students enrolled at other institutions through a partnership or consortium structure. Consortia should be well justified to enhance the goals and objectives of the training program. Consortium partners will be identified by the applicant organization, and each partner institution must identify faculty at their location who have agreed to serve as mentors.

Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicant organizations and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

This Notice of Funding Opportunity (NOFO) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective applicant organizations **MUST** consult the **Table of IC-Specific Information, Requirements and Staff Contacts (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)**, to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal
Resubmission
Revision

The OER Glossary (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

Need help determining whether you are doing a clinical trial? (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (*NIH Grants Policy Statement* - Institutional Research Training Grants (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the *NIH Grants Policy Statement* (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T35 short-term institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://web.archive.org/web/20250122105054/https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for

this to be an allowable cost.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicant organizations are encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html) for further information.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the *NIH Guide for Grants and Contracts,* and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://web.archive.org/web/20250122105054/https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of $25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

NIH grants policies as described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicant Organizations

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Local Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicant organizations should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- System for Award Management (SAM) (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) – Applicant organizations must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicant organizations must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research training program as the Training Program Director/Principal Investigator (Training PD/PI) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including individuals from underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) and Notice of NIH's Interest in Diversity, NOT-OD-20-031 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program consistent with applicable law, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11126).

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is programmatically distinct.

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82423))

Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program.When building a training team, programs should include faculty who are committed to training, mentoring, and providing inclusive, safe, accessible, and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

Trainees

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the *NIH Grants Policy Statement* (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

Short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not

eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the Table of Page Limits (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Project Summary/Abstract. Provide an abstract of the entire application. Include the objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term faculty), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Please name your file "Advisory_Committee.pdf".

The filename provided for each "Other Attachment" will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Training Budget

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) with the following additional modifications:

- Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program
- Faculty, Trainees, and Training Record
- Other Training Program
- Appendix - Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicant organizations to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Particular attention must be given to the required International **Training Data Tables** (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61169). Applicant organizations should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective trainee candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique background and skill set that will enhance training. The application should expand on the information in the

biosketch(es) to address how the PD/PI or PD/PI team has:

- The appropriate expertise (for example, a record of rigorous research), as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicant organizations should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees from all backgrounds including trainees from groups underrepresented in the biomedical sciences (e.g., see Notice of NIH's Interest in Diversity (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program

Program Faculty

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

- The efforts made to recruit a pool of prospective program faculty from a wide variety of backgrounds, for example, faculty from underrepresented groups, and a range of career stages and scientific disciplines relevant to the training goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences. Include the planned format, duration, and frequency of mentor training activities for program faculty and a description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples of relevant topics include, but are not limited to:
    - Aligning expectations.
    - Maintaining effective communication.
    - Fostering independence.
    - Assessing scholars' understanding of scientific research.
    - Enhancing professional development.
    - Addressing equity and inclusion.
    - Articulating your mentoring philosophy and plan.

Proposed Training

In addition to the information specified in the Application Guide, describe:

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development, and how these activities will address the program's training goals and objectives.
- How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicant organizations and trainees will be provided with information about the overall biomedical research workforce employment landscape, the variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.
- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities) that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

Training Program Evaluation

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is inclusive and supportive of trainee development .
- The program's procedures for responding to program evaluation findings.

Trainee Candidates and Retention Plans

Through the narrative and summaries of the information presented in the Training Data Tables (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within the program (i.e., retention), including those from underrepresented groups. Applicant organizations are encouraged to consult the NIH's website to identify promising retention practices (https://web.archive.org/web/20250122105054/https://extramural-diversity.nih.gov/building-participation/recruitment-retention) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

Institutional Environment and Commitment to Training

- The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing an inclusive, safe and supportive environment with procedures to ensure accountability and reporting of concerns. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the NOFO. Do not repeat information contained elsewhere in the application.

Training Outcomes

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required training tables (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm) . The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in Training Table 5 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree Training Table 8 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm)).
- The success of recent graduates transitioning to careers in the biomedical research workforce (Training Table 8). (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

Progress Report for Renewal Applications

For renewal applications include information in the “Program Overview” section to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. Highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote inclusive, safe, accessible and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

Faculty, Trainees, and Training Record

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting an inclusive and supportive scientific environment.
- Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also be described in the letter:

- Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- Supporting core facilities and technology resources and describing how they can be used to enhance training.
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting safe, accessible, and inclusive and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_ma regarding NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality research); ensuring the research facilities are accessible to trainees with disabilities; ensuring a positive, supportive, and inclusive research and training environment for individuals from all backgrounds.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-22-129 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-129.html)).
- Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- Supporting evaluation of the training program and procedures for responding to evaluation findings.

Other Training Program Section

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

PHS Assignment Request Form

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. contains information about Key Dates and times. Applicant organizations are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicant organizations must then complete the submission process by tracking the status of the application in the eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicant organizations are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement* (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). Paper applications will not be accepted.

Applicant organizations must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form.Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

See more tips (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://web.archive.org/web/20250122105054/https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

Post Submission Materials

Applicant organizations are required to follow the instructions for post-submission materials, as described in the policy (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82299).

Any instructions provided here are in addition to the instructions in the policy.

Substitute the term "scholars" for all references to "trainees" in the SF424 (R&R) Application Guide, and substitute the term "career development" for all references to "training" in the SF424 (R&R) Application Guide.

Section V. Application Review Information

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 (https://web.archive.org/web/20250122103054/https://grants.nih.gov/grants/guide/NIH_redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of trainee candidates, trainees, or faculty may not, in and of themselves, be used as factors in the evaluation of applications.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed.)

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of the merit of the training program and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major biomedical research training impact.

Training Program and Environment

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers?
- Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

- Does the application provide a compelling rationale for the proposed short-term research training program and include appropriate training goals and objectives relevant to the rationale? Are the objectives, design, direction, and quality of the proposed short-term research training program likely to ensure effective training?
- Are the proposed courses, structured training activities, mentoring, and research experiences - where applicable - appropriate for the level of trainees and the area(s) of science to be supported by the program? Do the program activities appropriately introduce trainees to transparent, rigorous, and reproducible research methodologies?
- If appropriate, does the program provide training in inter- or multi-disciplinary research and/or provide training in state-of-the-art or novel methodologies and techniques?
    - Is the proposed program of training likely to ensure that trainees will acquire knowledge and skills necessary to prepare them for a research career? Does the program include features likely to encourage short-term trainees to consider careers in health-related research?
- Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Do the PD(s)/PI(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee success?
- **For applications designating multiple PDs/PIs:**
    - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
    - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/PIs?

Preceptors/Mentors

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences?
- Do participating faculty appropriately promote the trainees' career progression?

- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

Trainees

- Does the proposed short-term training program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training goals and objectives? Are the outlined recruitment strategies likely to identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?
- Does the program have access to and the ability to recruit high quality, short-term trainees from the applicant institution or another health-professional school?
- Are the recruiting procedures and trainee selection criteria appropriate and well defined?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?

Training Record

- How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?

- **For applications that request short-term research training positions,** is there a record of retaining health professional trainees in research training or other research activities for at least two years?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Recruitment Plan to Enhance Diversity

Reviewers will examine the strategies to be used in the recruitment of prospective candidates from underrepresented groups.

For purposes of this review, "recruitment" refers to outreach efforts intended to encourage individuals to apply for the program. "Recruitment" does not mean the appointment or hiring of an individual into the program. For renewals, the committee may consider the program's account of past experiences, including successful and unsuccessful strategies, but may not use the race, ethnicity, or sex of program trainees appointed during the previous funding period as factors in the evaluation.

Training in the Responsible Conduct of Research

All applications for support under this NOFO must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format*** **-** Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (*A plan involving only on-line instruction is not acceptable.*); 2) ***Subject Matter*** **–** Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) ***Faculty Participation*** **-** Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) ***Duration of Instruction*** **-** Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) ***Frequency of Instruction*** **–** Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the short-term training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the short-term research training experience during the next project period?
- Does the program use current, evidence-informed training and mentoring approaches and continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

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.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by {LOCUS OF REVIEW} in accordance with NIH peer review policy and procedures (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications 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 an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board.

The following will be considered in making funding decisions, consistent with applicable law:

- 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.

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 Section 2.5.1. Just-in-Time Procedures. (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

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.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see Award Process. (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/pre-award-process.htm#award)

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690 (https://web.archive.org/web/20250122105054/https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (https://web.archive.org/web/20250122105054/https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
    - HHS recognizes that NIH research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates. (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandate

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See 2 CFR Part 200.340 Termination (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions-

suspension, termination, and withholding of support.htm).

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41171).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it (https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it) to learn more.

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://web.archive.org/web/20250122105054/https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61131).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data)

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/rppr/index.htm) annually. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the recipient institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

Other Reporting Requirements

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, are required for closeout of an award as described in the NIH Grants Policy Statement Section 8.6 Closeout (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications,

support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in achieving its goals, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

For programs involving undergraduate students:

- Successful completion of an undergraduate degree in a STEM field
- Pending application for and/or enrollment in an advanced degree program in a STEM field
- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field

For programs involving graduate students:

- Successful completion of a STEM graduate program
- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

For programs involving postdoctorates and early career investigators:

- Subsequent participation in a formal research training or career development program in a STEM field
- Subsequent participation in research or employment in a STEM field
- Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this NOFO, prospective applications **MUST** consult the **Table of IC-Specific Information, Requirements, and Staff Contacts (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)**, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://web.archive.org/web/20250122105054/https://www.era.nih.gov/need-help) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-480-7075

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

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Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Karen Robinson Smith

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Section VIII. Other Information

Recently issued trans-NIH policy notices (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/web/20250122105054/https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?01-03-25)
NIH Funding Opportunities and Notices (/web/20250122105054/https://grants.nih.gov/grants/guide/index.html)

NIH National Institutes of Health Office of Extramural Research
(/web/20250122105054/https://grants.nih.gov/grants/oer.htm)

(https://web.archive.org/web/20250122105054/https://www.hhs.gov/)
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Updates to NIH Institutional Training Grant Applications

This page provides details on the updates made to NIH institutional training grant applications for due dates on or after January 25, 2025.

On this page:

- Background
- Application Updates
- Peer Review Updates
- Notices, Reports, and Blogs

↑ Back to Top

Case: 25-1611 Case 1:25-cv-10787-WGY Document 172-7 Filed 05/19/25 Page 3 of 9 Entry ID: 6756750

Background

NIH has made significant investments to develop, implement, assess and disseminate innovative, effective approaches to research training and mentoring and to prepare trainees for a variety of career paths in the biomedical research workforce. Through these initiatives, the research community has identified the need for:

- Broader outreach activities to foster greater awareness of research training opportunities for potential trainees
- Increased mentorship opportunities to facilitate trainee success

NIH has leveraged the lessons of these initiatives to enhance institutional research training programs, including by enhancing opportunities to strengthen mentor training.

Applicability

The updates apply to applications that use the following activity codes:

- Institutional Training – T series, e.g., T15, T32, T34, T35, T37, T90/R90, TL1, TL4
- International Institutional Training – D43, D71, U2R
- Institutional Career Development – K12, KL2

Application Updates

The updates to NIH Institutional Training Grant Applications include two key changes:

1. Mentor training expectations are more clearly defined in the parent T32 Notice of Funding Opportunity (NOFO).
2. Institutional Training data tables were updated to reduce burden and promote consistent information collection across training programs.

March 2025 Update:

Case: 25-1611 Case 1:25-cv-10787-WGY Document 172-7 Filed 05/19/25 Page 4 of 9 Entry ID: 6756750

- *Recruitment Plans to Enhance Diversity are no longer required.*
- *Recruitment Plans to Enhance Diversity included in applications under review will not be evaluated or considered in funding decisions.*
- *A Trainee Diversity Report for institutional training grants, career development awards, and most research education grants is no longer required in Research Performance Progress Reports (RPPRs) and should not be included.*
- *The ability to generate the Trainee Diversity Report is no longer available to recipients.*

Defining Mentor Training Expectations in Training Programs

The Parent T32 NOFO incorporates new language outlining expectations for mentor training and oversight into the program considerations, application instructions, and review criteria.

Programs should consider the following, in addition to other evidence-informed curricula, as potential mentor training components and are encouraged to adapt to program and trainee needs:

- Aligning expectations
- Maintaining effective communication
- Fostering independence
- Assessing understanding
- Enhancing professional development
- Articulating your mentoring philosophy and plan

Reviewers will assess the mentor training expectations included in the application.

Updates to Data Tables

Institutional Training data tables were updated to reduce burden, focus on trainee outcomes, and promote consistent information collection across training programs. For example:

- Tables 1 and 2: Applicants are expected to provide data **only** for the training stage(s) reflected in the proposed program.

Case: 25-1611 Case 1:25-cv-10787-AK Document 172-7 Date Filed: 05/19/2025 Page: 5 of 9 Entry ID: 6756750

- Table 5 (Publications of Those in Training) was reorganized so that the first column is the trainee (instead of the faculty member), and applicants are now allowed to include interim research products to which the trainee contributed.
- Table 6 (Applicants, Entrants, and their Characteristics for the Past Five Years) will no longer ask for trainee characteristics related to prior academic and research experience.
  - ***March 2025 Update:*** *FORMS-I Training data tables 6a, 6b, and 7 have been revised to remove calculations for % underrepresented minorities.*
- Table 8 (Program Outcomes: Predoctoral and Postdoctoral) no longer includes Part II "Those Clearly Associated with the Training Grant."

Peer Review Updates

Institutional training awards retain the five scored review criteria. For example, for Training Grants (Ts), reviewers will continue to score Training Program and Environment, Training Program Director(s)/Principal Investigator(s), Preceptors/Mentors, Trainees, and Training Record when determining the overall impact score.

NIH has moved "Training in the Responsible Conduct of Research" from the "Additional Review Considerations" and is now included as an "Additional Review Criteria." As such, reviewers will now evaluate "Training in the Responsible Conduct of Research" when determining scientific and technical merit, and in providing an overall impact score.

Notices, Reports, and Blogs

Notices

- Reminder of Updates to NIH Training Grant Application Data Tables for Application Due Dates on or After January 25, 2025: NOT-OD-25-044 - December 10, 2024
- Reminder that Multiple Changes Affecting Extramural Applications and Review are Coming for Application Due Dates

Case: 25-1611 Case 1:25-cv-10787-WGY Document 1-2 Filed 05/19/25 Page 6 of 9 Entry ID: 6756750

on or After January 25, 2025: NOT-OD-25-035 - November 21, 2024

- Reminder: FORMS-I Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2025: NOT-OD-25-026 - November 18, 2024
- Updates to NIH Institutional Training Grant Applications for Due Dates on or After January 25, 2025: NOT-OD-24-129 – May 31, 2024
- Updates to NIH Training Grant Applications - Registration Open for June 5, 2024 Webinar: NOT-OD-24-124 – May 8, 2024

Blogs

- Open Mike Announcing updates to NIH Institutional Training Grant applications and required data tables – May 16, 2024

Resources

General

- How to Apply – Application Guide
- Data Tables: FORMS-I
- Drop-in-slides-Training-Grant-Application-Updates (PPTX, 585 KB) (February 25, 2025)

See Also

Webinars & Videos

- Updates to NIH Training Grant Applications webinar (June 5, 2024)

Contact

Case: 25-1611 Case 1:25-cv-10787-WGY Document 97-7 Date Filed: 05/19/2025 Page 7 of 9 Entry ID: 6756750

Email

For those with questions, please direct all inquiries to:
T32updates@mail.nih.gov

This page last updated on: March 25, 2025
For technical issues E-mail OER Webmaster

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Case: 25-1611 Case 1:25-cv-10787-WGY Document 72-7 Date Filed: 05/19/2025 Page 9 of 9

Site Map

Home

New To NIH

Funding

Grants Process

Policy & Compliance

News & Events

About Us

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

DATE: 3/11/2025

TO: Ken Callahan Senior Advisor Policy and Implementation

FROM: Matthew J. Memoli, MD, MS Acting Director, NIH

SUBJECT: Initial Actions Regarding President Trump's Executive Orders – INFORMATION

ISSUE

In response to the request to review President Trump's Executive Orders issued between [PLACEHOLDER] and [PLACEHOLDER], determine which were relevant to the Office of the Assistant Secretary for Health's programs and policies, and describe the actions taken for alignment.

EXECUTIVE SUMMARY

Upon review of President Trump's Executive Orders issued since January 20, 2025, [PLACEHOLDER] were relevant to the programs and policies of the NIH. The following outlines each relevant executive order and actions taken for alignment.

EO 14162 - Putting America First in International Environmental Agreements

Prioritize U.S. interests in international environmental agreements, withdrawing the U.S. from the Paris Climate Agreement and halting funding to related climate initiatives, while revoking the U.S. International Climate Finance Plan and directing relevant agencies to rescind policies linked to it.

Implementation: N/A
Further Considerations: N/A

EO 14171 - Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce

Reinstates and amends Executive Order 13957 to create a new Schedule Policy/Career for confidential, policy-determining, policy-making, or policy-advocating positions, ensuring these roles are accountable to the President and exempt from standard adverse action procedures.

Implementation:

1. Create a new Schedule Policy/Career for confidential, policy-determining, policy-making, or policy-advocating positions.
Action Taken: Awaiting implementation guidance from HHS.
Status: In Progress

2. Maintaining the Integrity of the Career SES

Action Taken: Review and Reclassification of SES Positions
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14179 - Removing Barriers to American Leadership in Artificial Intelligence

Aims to revoke previous policies that hinder AI innovation and establish a plan to sustain and enhance America's global dominance in AI, promoting economic competitiveness and national security.

Implementation:

1. Reporting Actions to Implement "Removing Barriers to American Leadership in Artificial Intelligence"
Action Taken: Data call to gather programmatic information related but not limited to statutes, regulations, guidance, intramural research, policies, public education documents and campaigns, communications, events, FACA committees, reports, other internal and external committees, and working groups.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14210 - Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative

Implement the "Department of Government Efficiency" workforce optimization initiative, focusing on reducing government waste, streamlining federal agencies, and eliminating non-essential positions and programs.

Implementation:

1. Submit Agency Reorganization Plans
Action Taken: 2/26/2025: Exec Sec sent email to department heads
Status: Not Started

2. Not-To-Exceed Appointments Expiring through May 3
Action Taken: Each ICO to submit employee NTE date with position description and impact if extension is not approved.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14168 - Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government

Directs federal agencies to recognize only two immutable sexes (male and female) and to enforce sex-based rights and protections accordingly, rejecting the concept of gender identity.

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative
Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.
Status: In Progress

2. Removing "X" Option from VAMI Forms
Action Taken: Update the Visitor Access Management Initiative (VAMI) system by replacing gender with sex and removing "X" as an option.
Status: Complete

3. Identify and Place Employees on Administrative Leave in Gender Ideology Positions
Action Taken: Seven employees were placed on administrative leave. Confirmed that NIH does not have any positions inculcating or promoting gender ideology. While the Sexual and Gender Minority Office (SGMRO) is technically on the NIH management organization chart, all positions in SGMRO are vacant, and NIH/DPCPSI has started the process to remove SGMRO from the DPCPSI organizational structure.
Status: Complete

4. Discussions with Tenure-Track Investigators Not on Administrative Leave
Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.
Status: In Progress

5. Changes to webpages, flyers, posters related to DEIA, gender
Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex.Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.
Status: Complete

6. Review of women's health or sex as a biological variable activities - Mar 20
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: In Progress

7. Review of women's health or sex as a biological variable activities - Mar 3
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

8. Remove Pronouns from Email, Outward Facing Media; Change 'Gender' to 'Sex'
Action Taken: System wide platforms, manuals disabled the use of pronouns, gender language (Zoom, Microsoft 365, NIH employee directory, email distribution lists, list servs, NIH rules of behavior, Visitor Access Management Initiative, nVistas, etc.).
Status: Complete

9. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated

direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

10. Ensure that data analyses align with administration guidance
Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.
Status: In Progress

11. Update agency forms for gender - clinical data forms
Action Taken: References to gender or to sex other than male/female will be removed from clinical data forms. A fast-track process for this effort has been established by our Office of Human Subjects Research Protection and our Institutional Review Board.
Status: In Progress

12. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts
Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications.
Status: In Progress

13. Review peer review activities and terminate any that promote or inculcate gender ideology
Action Taken: The NIH SGM Employee Resource Group and the SGM Scientific Interest Group was disbanded. CSR will identify and eliminate sub-topics that may not align with the E) guidance. The Reviewer Finder tool has been modified to remove all data on reviewer gender. CSR will not track demographics of its reviewers in their ~1200 peer review meetings and internal NIH dashboards for staff use have been modified to remove the ability to track gender.
Status: In Progress

14. Update FACA website to remove gender language
Action Taken: Removed phrase from the last sentence of the first paragraph of "Selection criteria for Advisory Committees" on the Office of Federal Advisory Committee Policy (OFACP) public website about including advisory committee members based on gender.

Status: Complete

15. Terminate Special Interest Groups that Inculcate Gender
Action Taken: Council of councils SGM Working Group is paused--will be disbanded once FACA Council activities are able to resume.
Status: In Progress

16. Revising inclusion of women in clinical research policy
Action Taken: Information on the inclusion of women in research related to implementation of Defending Women EO and OPM memo.
Status: In Progress

17. Review and terminate agency contracts that promote gender ideology
Action Taken: Women-related agency contracts were were fully terminated (6), updated activities (2), and modified language/data fields (39). Disseminate direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders. We engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. We provided data related to actions taken on both executive orders back up to HHS, including cost savings data. As a result of a court order, OALM ensured compliance by providing the notice to all NIH contractor organizations by the stated deadline.
Status: Complete

18. Remove gender identifiers from agency forms - intramural individual development plans
Action Taken: NIH is removing the gender identifiers from internal OIR electronic development plan systems.
Status: In Progress

19. Review of pending awards and terminate any that promote or inculcate gender ideology
Action Taken: Applications to be funded that currently refer to “gender” in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.
Status: In Progress

20. Review Notices of Funding Opportunity for Gender
Action Taken: NIH is currently reviewing all active and proposed Notices of Funding Opportunities and Notices of Special Interest to determine if they promote gender ideology and will take action as appropriate, including termination if needed.
Status: In Progress

21. Terminate Active Grants that Promote or Inculcate Gender Ideology
Action Taken: NIH is currently reviewing all active grants and supplements to determine if they promote gender ideology and will take action as appropriate.
Status: In Progress

22. Updating NIH Manual Chapter 1311 - Preventing and Addressing Harassment and Inappropriate Conduct
Action Taken: Updated NIH Manual Chapter 1311 to remove references to gender.
Status: Complete

23. Terminate trainings on gender ideology

Action Taken: The only thing identified was the Women in Leadership program, which doesn't meet this definition. Confirmed that we do not have any other trainings that inculcate or promote gender ideology.
Status: Complete

24. NIAID Grants Related to Gender - Additional Consideration
Action Taken: Correspondence about NIAID grants related to gender, surgery, hormone therapy.
Status: Additional Consideration

25. List of Women Related Protocols
Action Taken: NIH is reviewing all survey instruments, forms, protocols, and clinical guidelines to ensure compliance with EO 14168.
Status: In Progress

26. Terminate Special Interest Groups that Inclucate Gender
Action Taken: Employee resource groups or special emphasis programs that inculcate or promote gender ideology have been terminated.
Status: Complete

27. Guidance on Implementing Section 3(e) of Executive Order 14168 (Defending Women) in Accordance with the Paperwork Reduction Act and the Privacy Act
Action Taken: Guidance specifies how agencies can implement Section 3(e) of EO 14168 (Defending Women) in compliance with the Paperwork Reduction Act and the Privacy Act in a timely manner.
Status: In Progress

28. Withdraw Any Forms, Documents...That Inculcate or Promote Gender Ideology
Action Taken: NIH forms have been updated to remove gender identification.
Status: Complete

29. Terminate Active Contracts that Promote or Inculcate Gender Ideology
Action Taken: Review all agency contracts and terminate any that promote or inculcate gender ideology.
Status: In Progress

30. Report on training activities
Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but likely Defending Women, DEIA.
Status: Complete

31. Provide all updated or terminated reports that inculcate or promote gender ideology.
Action Taken: Updated or terminated reports that inculcate or promote gender ideology.
Status: Complete

32. Review of gender ideology positions and offices
Action Taken: Verification that Sexual and Gender Minority Office (SGMRO) has been disbanded and there are no current gender ideology job positions related to SGMRO
Status: Complete

33. Removal of Gender Related Outward Facing Media
Action Taken: Removed outward facing media (websites, social media accounts, etc.) that inculcates

or promotes gender ideology. Implemented a freeze on external communication (websites, social media, press releases, listservs, individual public inquiries on sensitive health topics).
Status: Complete

34. Removal of webpages related to DEIA and gender ideology
Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.
Status: Complete

35. Review of women's health or sex as a biological variable activities - Feb 20
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

36. Review of women's health or sex as a biological variable activities - Feb 12
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

37. Review of women's health or sex as a biological variable activities - Feb 6
Action Taken: An initial review of current and planned 'women's health or sex as a biological variable' official agency activities identified 92 current or planned activities.
Status: Complete

38. Tribal Sovereignty - Additional Consideration
Action Taken: Information on tribal sovereignty related to implementation of Defending Women EO and OPM memo.
Status: Additional Consideration

39. Change gender to sex in NIH Databook
Action Taken: NIH Databook has updated about 16 reports that use "gender" or "women" in the title and data.
Status: Complete

40. Ensure that intimate spaces designated for women, girls,or females (or for men, boys, or males) are designated by biological sex and not gender identity.
Action Taken: NIH has certified that gender neutral restrooms now use the terminology of men and women.
Status: Complete

41. Reporting on current or planned women's health and sex as a biological variable official agency activities
Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans , FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).
Status: Complete

42. Update Common Data Element (CDE) repository to address use of 'gender' and 'sex'
Action Taken: The Common Data Element (CDE) Repository contains a small number of CDEs that refer to gender; the National Library of Medicine (NLM) recommends adding a disclaimer to those items to clarify that "gender" should not be used to as a substitute for the data element "sex."
Status: Complete

43. Terminate intramural gender ideology programs
Action Taken: NIH is currently reviewing all intramural programs to determine if they promote gender ideology and will take action as appropriate, including termination if needed, by the 30-day deadline.
Status: In Progress

44. Terminate applications that include gender ideology
Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Return to In Person Work

Mandates that all federal executive branch employees return to full-time in-person work at their duty stations, with department heads allowed to make necessary exemptions.

Implementation:

1. Guidance for Return to In-Person Work
Action Taken: Communication sent to supervisory employee's w/o exemption to return on 2/24.Preparing addition information to employees remote within 50-mile radius of office return 3/17. Provided guidance to all ICs and offices that these staff must return to the office unless they have an exemption.
Status: In Progress

2. Action Updates for Return to In-Person Work
Action Taken: Summary of Office of Research Facilities-led activities related to return to In-Person work.
Status: In Progress

3. Updates to Return to Office
Action Taken: NED updates for all employees returning to office
Status: In Progress

4. Return to Office Guidance
Action Taken: Guidance on the return to Office
Status: Complete

5. Guidance on Exempting Military and Foreign Service Spouses from Return to Work
Action Taken: Guidance on Exempting Military and Foreign Service Spouses from Return to Work
Status: Additional Consideration

6. Approval to Proceed with Procurements to Support In-Person Work
Action Taken: Institutes and Centers are directed to carefully document, justify and support their minimal, immediate needs, in coordination with their acquisition staff. Reporting should include detailed itemizations of what funds are being obligated for.

Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14151 - Ending Radical and Wasteful Government DEI Programs & Preferencing

Terminates all federal diversity, equity, and inclusion (DEI) programs, mandates, and policies, aiming to replace them with a merit-based system that rewards individual skills and performance.

Implementation:

1. Discussions with Tenure-Track Investigators Not on Administrative Leave
Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.
Status: In Progress

2. Placed DEIA Employees on Administrative Leave
Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.
Status: Complete

3. Pause Approving Invoices or Completing Receiving for DEI Activities Performed by Contractors
Action Taken: In accordance with HHS guidance, OALM paused all payment of invoices related to DEI activities, and is coordinating with HHS on special review of these invoices prior to payment.
Status: Complete

4. Removal of DEIA Related Language from CY2025 Performance Plan
Action Taken: Updating Performance Plans by March 25, 2025.Review all remaining 2025 Performance Elements for Supervisory and Non-Supervisory employees and remove any DEIA related language. Establish new 2025 Performance plans.
Status: Complete

5. Changes to webpages, flyers, posters related to DEIA, gender
Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex.Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.
Status: Complete

6. Data Call to Redesignate CHCO Positions
Action Taken:
Status: In Progress

7. Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies.
Action Taken: Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies, Rescission of "any guidance, instruction, recommendation, or document issued by the IWG is withdrawn as no longer representative of governmental policy related to the Presidential

Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking).” NIH is awaiting HHS direction as to whether HHS and NIH policy should be rescinded.
Status: In Progress

8. Termination of NIH Distinguished Scholars Program
Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research.
Status: Complete

9. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

10. Ensure that data analyses align with administration guidance
Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.
Status: In Progress

11. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts
Action Taken: Removed language regarding NIH’s Interest in Diversity from Eligibility section of Notices of Funding Opportunities (“NOFOs”). Similar statements are being manually removed in other sections as they are identified. Removed language regarding “Plans for Enhancing Diversity (PEDP)” from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications.
Status: In Progress

12. Removal of DEI-Related Content from Microsoft 365
Action Taken: ICOs reviewed and verified their identified sites and content and ensured proper

records management:
Status: Complete

13. Summary of DEIA Activities January 21 through February 6, 2025
Action Taken: This is a summary of DEIA activities January 21 through February 6, 2025.
Status: Additional Consideration

14. Do Not Reinstate Contracts Terminated between Jan. 20th – Jan. 31st
Action Taken: Terminated 31 contracts focusing on DEI related activities impacting funding to the vendor since January 20, 2025. Cost savings is roughly $6 million. The START document library includes additional information (email and spreadsheet).
Status: Complete

15. Compile a List of All DEI Websites and Equity Plans
Action Taken: List of all ICO DEI webpages and equity plans was compiled.
Status: Complete

16. Report on training activities
Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but likely Defending Women, DEIA.
Status: Complete

17. Removal of webpages related to DEIA and gender ideology
Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Hiring Freeze

Imposes a freeze on the hiring of federal civilian employees across the executive branch, with exceptions for military personnel, national security, public safety, and certain other roles, aiming to reduce the federal workforce through efficiency improvements and attrition.

Implementation:

1. Federal Civilian Hiring Freeze
Action Taken: Paused efforts to develop process for manage hiring freeze exceptions to wait further information on the OPM Guidance on Agency RIF and Reorganization Plans. Canceled the Summer Internship Program for 2025.Freeze on the hiring of federal civilian employees as directed by the President on 1/20/2025.
Status: Complete

2. Request for Agency Performance Management Data
Action Taken: Agencies should report to on employees with less than fully successful in the last three years.
Status: In Progress

3. Hiring Exemption Request Process
Action Taken: NIH is initiating a data call for Vacant Funded/Approved Positions and Hiring

Exemptions.
Status: In Progress

4. Not-To-Exceed Appointments Expiring through May 3
Action Taken: Each ICO to submit employee NTE date with position description and impact if extension is not approved.
Status: In Progress

5. Allowing Renewal of Current NIH Fellows
Action Taken: Renewal of current fellows is allowable and should proceed - non-FTE fellows (IRTAs, CRTAs, and Visiting Fellows). Pause on the recruitment and on-boarding of non-FTE fellows remains in effect.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14170 - Reforming the Federal Hiring Process And Restoring Merit To Government Service ("Restoring Merit")

Aims to overhaul the federal hiring process by prioritizing merit, practical skills, and dedication to the Constitution, while eliminating impermissible factors such as race, sex, and commitment to illegal racial discrimination or gender identity.

Implementation:

1. Review hiring practices and committee charters and processes
Action Taken: Review NIH hiring practices to assure they are in compliance and that all job announcements are in compliance as well as all hiring committee charters and processes.
Status: In Progress

2. Request for Agency Performance Management Data
Action Taken: Agencies should report to on employees with less than fully successful in the last three years.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Regulatory Freeze Pending Review

Directs all executive departments and agencies to halt the proposal or issuance of new rules until they are reviewed and approved by newly appointed department or agency heads, with exceptions for emergency situations.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Restoring Accountability for Career Senior Executives

The Director of OPM and Director of OMB shall issue SES Performance Plans that agencies must adopt;

prioritize accountability in the SES system; reassign agency SES members to align with the administration's agenda; terminate existing Executive Resources Board (ERB) and Performance Review Board and create new boards; and agency heads should take action to address SES officials who do not carry out their duties consistently with the administration's principles.

Implementation:

1. Maintaining the Integrity of the Career SES
Action Taken: Review and Reclassification of SES Positions
Status: In Progress

2. Guidance on Career Reserved SES Positions and Agency Redesignation Requests
Action Taken: Agencies should 1) develop a revised, proposed list of career reserved positions, consistent with agency organic statutes and guidance and 2) submit a single request to OPM to redesignate each current career reserved position that is not on the list.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Declaring A National Emergency At The Southern Border Of The United States

Declares a national emergency due to threats such as cartels, criminal gangs, and terrorists, and directs the Department of Defense and Armed Forces to support efforts to secure the southern border.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Expanding Migrant Operations Center at Naval Station Guantanamo Bay to Full Capacity

Directs the Secretary of Defense and the Secretary of Homeland Security to expand the center to provide additional detention space for high-priority criminal aliens unlawfully present in the United States

Implementation: N/A
Further Considerations: N/A

EO 14148 - Initial Rescissions of Harmful Executive Orders and Actions

Rescinds several executive orders from the previous administration, focusing on reversing policies related to diversity, equity, and inclusion (DEI), climate change, and immigration.

Implementation: N/A
Further Considerations: N/A

EO 14155 - Withdrawing The United States From The World Health Organization

Directs the U.S. to withdraw from the WHO due to its mishandling of global health crises, failure to implement reforms, and disproportionate financial demands, while establishing new U.S. leadership positions to safeguard public health and biosecurity.

Implementation:

1. Evaluating NIH WHO Collaborating Centers
Action Taken: Reviewing the 3 NIH WHO Collaborating Centers and putting a pause on any funding that may be going to the WHO.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14158 - Establishing and Implementing the President's Department of Government Efficiency

Creates the Department of Government Efficiency (DOGE) to modernize federal technology and software, aiming to maximize governmental efficiency and productivity.

Implementation:

1. Purchase Card Reinstatements
Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit card spend to the minimum emergency amount.
Status: Complete

2. Not-To-Exceed Appointments Expiring through May 3
Action Taken: Each ICO to submit employee NTE date with position description and impact if extension is not approved.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14173 - Ending Illegal Discrimination and restoring merit-based opportunity

Eliminates all forms of illegal discrimination in federal employment and contracting, promoting a merit-based system that prioritizes skills, qualifications, and performance.

Implementation:

1. Eliminate all illegal discrimination in federal employment and contracting.
Action Taken: We are carefully looking at all NIH hiring practices to assure they are in compliance and that all job announcements are in compliance as well as all hiring committee charters and processes.
Status: In Progress

2. Align Programs for American Indians and Alaska Natives with the Administration's Priorities
Action Taken: Agencies added their program-specific authorities and summarize the program in the guidance for OGC review.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14177 - President's Council of Advisors on Science and Technology – The White House

Reestablishes the President's Council of Advisors on Science and Technology (PCAST) to provide guidance on science, technology, and innovation policy, focusing on areas like artificial intelligence and quantum computing.

Implementation: N/A
Further Considerations: N/A

EO 14180 - Council to Assess the Federal Emergency Management Agency

Establishes a review council to evaluate FEMA's efficacy, priorities, and competence, and to recommend improvements or structural changes to enhance disaster response and recovery.

Implementation: N/A
Further Considerations: N/A

EO 14181 - Emergency Measures to Provide Water Resources in California and Improve Disaster Response in Certain Areas – The White House

Directs federal agencies to take immediate action to ensure adequate water resources in Southern California and improve disaster response, including overriding any state or local policies that hinder these efforts.

Implementation: N/A
Further Considerations: N/A

EO 14183 - Prioritizing Military Excellence and Readiness

Directs the Department of Defense to update policies to exclude individuals with gender dysphoria from military service, citing concerns over unit cohesion, mental and physical readiness, and overall military effectiveness.

Implementation: N/A
Further Considerations: N/A

EO 14184 - Reinstating Service Members Discharged Under the Military's COVID-19 Vaccination Mandate – The White House

Directs the Secretary of Defense and the Secretary of Homeland Security to reinstate service members who were discharged solely for refusing the COVID-19 vaccine, allowing them to return to their former rank with full back pay and benefits.

Implementation: N/A
Further Considerations: N/A

EO 14185 - Restoring America's Fighting Force

Eliminate race- and sex-based preferences within the U.S. Armed Forces, abolish Diversity, Equity, and

Inclusion (DEI) offices, and promote a merit-based, color-blind system to enhance military effectiveness and readiness.

Implementation: N/A
Further Considerations: N/A

EO 14188 - Additional Measures to Combat Anti-Semitism

Directs federal agencies to use all legal tools to prosecute and hold accountable those responsible for anti-Semitic harassment and violence, especially in schools and on campuses.

Implementation: N/A
Further Considerations: N/A

EO 14189 - Celebrating America's 250th Birthday – The White House

Establishes the White House Task Force on Celebrating America's 250th Birthday to plan and execute a grand celebration for the 250th anniversary of American Independence on July 4, 2026, and to honor the history of the nation.

Implementation: N/A
Further Considerations: N/A

EO 14191 - Expanding Educational Freedom and Opportunity for Families

Directs states and relevant agencies to promote expanded educational opportunities for K-12 education.

Implementation: N/A
Further Considerations: N/A

EO 14192 - Unleashing Prosperity through Deregulation – The White House

Directs all agencies, unless prohibited by law, to identify at least 10 existing regulations to be repealed every time it proposes a new regulation.

Implementation: N/A
Further Considerations: N/A

EO 14199 - Withdrawing the United States From and Ending Funding to Certain United Nations Organizations and Reviewing United States Support to All International Organizations

Withdraw the U.S. from certain United Nations organizations, halt funding, and review all U.S. support for international organizations to align with American interests.

Implementation:

1. Reviewing NIH programs for any involvement in the United Nations
Action Taken: We are reviewing NIH programs for any involvement in the United Nations and will take appropriate action.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14084 - Promoting the Arts, the Humanities and Museum and Library Services

We will enhance to high-quality arts and humanities education and programming with the aim of enabling every child in America to obtain the broad creative skills and enrichment vital to succeed.

Implementation:

1. Request information on activities relevant to Promoting the Arts, the Humanities, and Museum and Library Services.
Action Taken: An NIH-internal data call regarding ICO activities relevant to EO 14084 (Promoting the Arts, the Humanities, and Museum and Library Services) was sent to P&E Principals and Alternates on Tuesday, February 25th. Responses have been compiled and are attached.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14187 - Protecting Children from Chemical and Surgical Mutilation (Protecting Children EO)

The United States will not fund, sponsor, promote, assist, or support the so-called "transition" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

Implementation:

1. Prohibit Federal Funding, Sponsoring, Promoting, Assisting, or Supporting the So-called 'Transition' of a Child from One Sex to Another."
Action Taken: NIH will identify research that promotes chemical and surgical mutilation, and some award activities may be suspended as a result. NIH will identify research that promotes chemical and surgical mutilation, and some award activities may be suspended as a result.
Status: Additional Consideration

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14219 - Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Regulatory Initiative

Focus the executive branch's limited enforcement resources on regulations squarely authorized by constitutional Federal statutes, and to commence the deconstruction of the overbearing and burdensome administrative state. Ending Federal overreach and restoring the constitutional separation of powers is a priority of my Administration.

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative
Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Presidential Action - Honoring Jocelyn Nungaray

The Anahuac National Wildlife Refuge, a scenic area for coastal wildlife and recreation along the Gulf of America near Jocelyn's home in Texas, will forever honor and preserve the memory of a beautiful American, Jocelyn Nungaray.

Implementation: N/A
Further Considerations: N/A

EO 14222 - Implementing the President's "Department of Government Efficiency" Cost Efficiency Initiative

This order commences a transformation in Federal spending on contracts, grants, and loans to ensure Government spending is transparent and Government employees are accountable to the American public.

Implementation:

1. Data Call: GSA Non-Essential Contracts
Action Taken: Coordinated with the NIH Director to established categories of spend that aligned with Presidential Appointee priorities and could continue, established a reporting system that categorizes how the NIH Acquisition Workforce is obligating funds within these categories.Established a contract approval process for routing individual requests for consideration of other procurement requirements to the NIH Director for mission critical needs that may not fit squarely within an approved spend category.Paused the issuance of any new Contracting Officer warrants or other Delegations of Procurement Authority.Coordinated the termination of 113 non-essential contract awards for an estimated cost savings of approximately $14.6M thus far. Additional reviews seeking further cost savings opportunities remain ongoing.Coordinated with HHS to provide data that will be publicly posted regarding NIH's justifications for certain contracts are mission critical.Developed a system to provide Department of Government Efficiency staff with weekly reports detailing all NIH contracting activities, and OALM advised NIH Dr. Memoli reviewed and approved the contracts in question.
Status: Complete

2. Purchase Card Reinstatements
Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit card spend to the minimum emergency amount.
Status: Complete

3. Data Call: Reporting to OPM FY 2024 Taxpayer-Funded Union Time Use
Action Taken:
Status: In Progress

4. Data Call: Taxpayer-Funded Union Time Information
Action Taken:
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14169 - Reevaluating and Realigning United States Foreign Aid

It is the policy of United States that no further United States foreign assistance shall be disbursed in a manner that is not fully aligned with the foreign policy of the President of the United States. 90-day pause in United States foreign development assistance for assessment of programmatic efficiencies and consistency with United States foreign policy. Reviews of United States foreign assistance programs. Determinations. Resumption of paused development assistance funding.Waiver.

Implementation:

1. Review of NIH support for foreign research
Action Taken: OPERA and OER leadership, in consultation with Fogarty International Center and the Office of General Counsel are finalizing a decision memo confirming the applicability of this EO to NIH financial assistance mechanisms.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14204 - Addressing Egregious Actions of the Republic of South Africa

In shocking disregard of its citizens' rights, the Republic of South Africa (South Africa) recently enacted Expropriation Act 13 of 2024 (Act), to enable the government of South Africa to seize ethnic minority Afrikaners' agricultural property without compensation. This Act follows countless government policies designed to dismantle equal opportunity in employment, education, and business, and hateful rhetoric and government actions fueling disproportionate violence against racially disfavored landowners.

Implementation:

1. Researching the Applicability of 14204 to NIH
Action Taken: OER and OPERA is working with FIC and OGC on a decision memo confirming the applicability of this EO to NIH financial assistance mechanisms.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

EO 14182 - Enforcing the Hyde Amendment

It is the policy of the United States, consistent with the Hyde Amendment, to end the forced use of Federal taxpayer dollars to fund or promote elective abortion

Implementation: N/A
Further Considerations: N/A

Presidential Action - Amendment To Duties To Address The Flow Of Illicit Drugs Across Our Northern Border

Adjusts the tariffs imposed on articles of Canada in Executive Order 14193 of February 1, 2025

Implementation: N/A

Further Considerations: N/A

Presidential Action - Addressing Risks from Perkins Coie LLP

Suspends active security clearances and ceases provision of Government goods to Perkins Coie, terminates existing contracts and requires Government contractors to disclose any business with Perkins Coie, directs agencies to refrain from hiring Perkins Coie employees and limits their access to Federal buildings, and directs EEOC to investigate racial discrimination at large law firms

Implementation: N/A
Further Considerations: N/A

Presidential Action - Amendment To Duties To Address The Flow Of Illicit Drugs Across Our Southern Border

Adjusts the tariffs imposed on articles of Mexico in Executive Order 14194 of February 1, 2025

Implementation: N/A
Further Considerations: N/A

Presidential Action - Establishment Of The Strategic Bitcoin Reserve And United States Digital Asset Stockpile

Establishes a Strategic Bitcoin Reserve and a United States Digital Asset Stockpile that can serve as a secure account for orderly and strategic management of the United States' other digital asset holdings

Implementation: N/A
Further Considerations: N/A

Presidential Action - Restoring Public Service Loan Forgiveness

The Secretary of Education shall propose revisions to 34 C.F.R. 685.219, Public Service Loan Forgiveness Program, in coordination with the Secretary of the Treasury as appropriate, that ensure the definition of "public service" excludes organizations that engage in activities that have a substantial illegal purpose.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Establishing The White House Task Force On The FIFA World Cup 2026

Establishes a WH task force to assist in the planning, organization, and execution of the events surrounding the 2025 FIFA Club World Cup and the 2026 FIFA World Cup.

Implementation: N/A
Further Considerations: N/A

EO 14228 - Further Amendment to Duties Addressing the Synthetic Opioid Supply Chain in the People's Republic of China

Increases tariffs on goods from the People's Republic of China due to that nation's perceived failure to adequately address the flow of synthetic opioids, such as fentanyl, into the United States.

Implementation: N/A
Further Considerations: N/A

EO 14194 - Amendment to Duties to Address the Situation at our Southern Border

Aims to address the situation at the U.S. southern border by imposing additional duties on products imported from Mexico, with the stated goal of pressuring Mexico to take stronger actions against illegal immigration and drug trafficking.

Implementation: N/A
Further Considerations: N/A

EO 14223 - Addressing The Threat To National Security from Imports of Timber, Lumber

Aims to ensure reliable, secure, and resilient domestic supply chains of timber, lumber, and their derivative products.

Implementation: N/A
Further Considerations: N/A

EO 14225 - Immediate Expansion of American Timber Production

Aims to increase domestic timber production to protect our national and economic security.

Implementation: N/A
Further Considerations: N/A

EO 14224 - Designating English as the Official Language of The United States

Formalizes English as the nation's official language.

Implementation: N/A
Further Considerations: N/A

EO 14221 - Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information

Increases transparency in healthcare pricing, allowing consumers to make more informed decisions.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Suspension of Security Clearances and Evaluation of Government Contracts

Protect national security by addressing potential risks associated with individuals holding security clearances and companies with government contracts.

Implementation: N/A
Further Considerations: N/A

EO 14220 - Addressing the Threat to National Security From Imports of Copper

Ensures a reliable, secure, and resilient domestic copper supply chain.

Implementation: N/A
Further Considerations: N/A

Presidential Action - President Trump Takes Decisive Action to Deliver Relief to Kentucky

Provide federal assistance to Kentucky in the aftermath of a disaster or emergency.

Implementation: N/A
Further Considerations: N/A

Presidential Action - America First Investment Policy

Memorandum that prioritizes the interests of American workers and businesses in international trade.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Defending American Companies and Innovators From Overseas Extortion and Unfair Fines and Penalties

Safeguards U.S. economic interests by preventing foreign entities from using unfair practices to harm American businesses.

Implementation: N/A
Further Considerations: N/A

EO 14217 - Commencing the Reduction of the Federal Bureaucracy

Aims to reduce the size of the Federal Government to minimize government waste and abuse, reduce inflation, and promote American freedom and innovation.

Implementation: N/A
Further Considerations: N/A

Proclamation 10898 - 80th Anniversary of the Battle of Iwo Jima

Serves to commemorate and honor the historical significance of the Battle of Iwo Jima.

Implementation: N/A
Further Considerations: N/A

Presidential Action - President Trump Announces Appointments to Council of Governors

Appoints a bipartisan group of state leaders tasked with strengthening state-federal partnerships on key national security, disaster response, and military coordination issues to the Council of Governors.

Implementation: N/A
Further Considerations: N/A

EO 14218 - Ending Taxpayer Subsidization of Open Borders

Aims to stop federal funding from supporting programs that benefit undocumented immigrants or policies that facilitate illegal immigration.

Implementation: N/A
Further Considerations: N/A

EO 14215 - Ensuring Accountability for All Agencies

Aims to increase accountability and transparency within federal agencies.

Implementation: N/A
Further Considerations: N/A

EO 14216 - Expanding Access to In Vitro Fertilization

Ensure reliable access to IVF treatment, including by easing unnecessary statutory or regulatory burdens to make IVF treatment drastically more affordable.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Radical Transparency About Wasteful Spending

This memorandum aims to enhance public awareness and accountability concerning government spending through increased transparency regarding wasteful expenditures.

Implementation: N/A
Further Considerations: N/A

Proclamation 10897 - President George Washington's Birthday, 2025

Commemorates George Washington's legacy, promotes civic values, and fosters national unity.

Implementation: N/A
Further Considerations: N/A

Presidential Action - President Donald J. Trump Approves Kentucky Emergency Declaration

Authorizes federal assistance to supplement state and local response efforts in Kentucky during an emergency or disaster.

Implementation: N/A
Further Considerations: N/A

EO 14214 - Keeping Education Accessible and Ending Covid-19 Vaccine Mandates in Schools

EO 14214 aims to prevent schools and universities from requiring COVID-19 vaccination for students, citing concerns about personal freedom, parental authority, and access to education.

Implementation: N/A
Further Considerations: N/A

EO 14213 - Establishing the National Energy Dominance Council

Establishes the National Energy Dominance Council to advise the President on how to expand domestic energy production and reduce reliance on foreign sources.

Implementation: N/A
Further Considerations: N/A

EO 14212 - Establishing the President's Make America Healthy Again Commission

Establishes the President's Make America Healthy Again Commission to address and improve the health of Americans, particularly children, by focusing on reversing chronic diseases.

Implementation: N/A
Further Considerations: N/A

EO 14211 - One Voice for America’s Foreign Relations

Aims to ensure that all individuals involved in implementing the President's foreign policy do so under his authority and direction, with a unified and consistent voice.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Nominations Sent to the Senate

Officially submits a list of nominees for various government positions to the Senate for confirmation.

Implementation: N/A
Further Considerations: N/A

Proclamation 10895 - Adjusting Imports of Aluminum into The United States

Adjusts tariffs on aluminum imports to protect American industries and jobs from the harmful effects of unfair trade practices.

Implementation: N/A
Further Considerations: N/A

Presidential Action - President Trump Announces the President's Intelligence Advisory Board

Establishes a board to advise the President on intelligence matters.

Implementation: N/A
Further Considerations: N/A

Proclamation 10896 - Adjusting Imports of Steel into The United States

Aims to adjust steel imports into the United States to protect national security and domestic steel industries.

Implementation: N/A
Further Considerations: N/A

EO 14209 - Pausing Foreign Corrupt Practices Act Enforcement to Further American Economic and National Security

Aims to temporarily pause certain Foreign Corrupt Practices Act enforcement actions to prioritize American economic and national security interests.

Implementation: N/A
Further Considerations: N/A

EO 14207 - Eliminating the Federal Executive Institute

Aims to eliminate the Federal Executive Institute to reduce federal spending and streamline government operations.

Implementation: N/A
Further Considerations: N/A

EO 14208 - Ending Procurement and Forced Use of Paper Straws

Aims to eliminate the federal government's procurement and mandatory use of paper straws.

Implementation: N/A
Further Considerations: N/A

Proclamation 10894 - Gulf of America Day, 2025

Proclamation 10894 aims to recognize and celebrate the importance of the Gulf of Mexico region to the United States, while also promoting the use of the name "Gulf of America" as a preferred alternative.

Implementation: N/A
Further Considerations: N/A

EO 14206 - Protecting Second Amendment Rights

Aims to protect and defend Second Amendment rights by directing federal agencies to uphold those rights

and prevent unlawful infringement.

Implementation: N/A
Further Considerations: N/A

EO 14205 - Establishment of The White House Faith Office

Establishes the White House Faith Office to strengthen partnerships between the government and faith-based organizations to address social issues.

Implementation: N/A
Further Considerations: N/A

Presidential Action - President Trump Announces Appointments to the White House Faith Office

Announces Appointments to the White House Faith Office

Implementation: N/A
Further Considerations: N/A

EO 14203 - Imposing Sanctions on the International Criminal Court

Aims to impose sanctions on the International Criminal Court (ICC) personnel involved in investigations or prosecutions of U.S. persons or those of U.S. allies.

Implementation: N/A
Further Considerations: N/A

EO 14202 - Eradicating Anti-Christian Bias

Aims to eliminate perceived anti-Christian bias within federal programs and policies.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Memorandum for the Heads of Executive Departments and Agencies

Aims to stop federal funding of NGOs that undermine U.S. interests and align future funding with national priorities.

Implementation: N/A
Further Considerations: N/A

EO 14201 - Keeping Men Out of Women's Sports

Aims to prohibit biological males from participating in women's sports to preserve fairness and protect opportunities for female athletes.

Implementation: N/A
Further Considerations: N/A

Presidential Action - Amendment to Duties Addressing the Synthetic Opioid Supply Chain in the People's Republic of China

Amends a previous executive order (*Executive Order 14195: Imposing Duties To Address the Synthetic Opioid Supply Chain in the People's Republic of China*) to remove the *de minimis* exemption for tariffs on certain goods from China related to the synthetic opioid supply chain, once the Commerce Secretary certifies efficient tariff collection systems are in place.

Implementation: N/A
Further Considerations: N/A

Presidential Action - U.S. Hostage and Wrongful Detainee Day, 2025

Proclaims March 9, 2025, as U.S. Hostage and Wrongful Detainee Day

Implementation: N/A
Further Considerations: N/A

MEMO OPM - OPM Memo: Initial Guidance Regarding President Trump's Executive Order Defending Women

The memorandum from Charles Ezell, Acting Director of the U.S. Office of Personnel Management, provides initial guidance to federal agencies on complying with President Trump's Executive Order to end federal funding and promotion of gender ideology, with specific actions and deadlines for implementation.

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative
Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.
Status: In Progress

2. Removing "X" Option from VAMI Forms
Action Taken: Update the Visitor Access Management Initiative (VAMI) system by replacing gender with sex and removing "X" as an option.
Status: Complete

3. Identify and Place Employees on Administrative Leave in Gender Ideology Positions
Action Taken: Seven employees were placed on administrative leave. Confirmed that NIH does not have any positions inculcating or promoting gender ideology. While the Sexual and Gender Minority Office (SGMRO) is technically on the NIH management organization chart, all positions in SGMRO are vacant, and NIH/DPCPSI has started the process to remove SGMRO from the DPCPSI organizational structure.
Status: Complete

4. Discussions with Tenure-Track Investigators Not on Administrative Leave
Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.

Status: In Progress

5. Changes to webpages, flyers, posters related to DEIA, gender
Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex.Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.
Status: Complete

6. Review of women's health or sex as a biological variable activities - Mar 20
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: In Progress

7. Review of women's health or sex as a biological variable activities - Mar 3
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

8. Remove Pronouns from Email, Outward Facing Media; Change 'Gender' to 'Sex'
Action Taken: System wide platforms, manuals disabled the use of pronouns, gender language (Zoom, Microsoft 365, NIH employee directory, email distribution lists, list servs, NIH rules of behavior, Visitor Access Management Initiative, nVistas, etc.).
Status: Complete

9. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

10. Ensure that data analyses align with administration guidance
Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.
Status: In Progress

11. Update agency forms for gender - clinical data forms
Action Taken: References to gender or to sex other than male/female will be removed from clinical data forms. A fast-track process for this effort has been established by our Office of Human Subjects Research Protection and our Institutional Review Board.
Status: In Progress

12. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts
Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in

other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications.
Status: In Progress

13. Review peer review activities and terminate any that promote or inculcate gender ideology
Action Taken: The NIH SGM Employee Resource Group and the SGM Scientific Interest Group was disbanded. CSR will identify and eliminate sub-topics that may not align with the E) guidance. The Reviewer Finder tool has been modified to remove all data on reviewer gender. CSR will not track demographics of its reviewers in their ~1200 peer review meetings and internal NIH dashboards for staff use have been modified to remove the ability to track gender.
Status: In Progress

14. Update FACA website to remove gender language
Action Taken: Removed phrase from the last sentence of the first paragraph of "Selection criteria for Advisory Committees" on the Office of Federal Advisory Committee Policy (OFACP) public website about including advisory committee members based on gender.
Status: Complete

15. Terminate Special Interest Groups that Inculcate Gender
Action Taken: Council of councils SGM Working Group is paused--will be disbanded once FACA Council activities are able to resume.
Status: In Progress

16. Revising inclusion of women in clinical research policy
Action Taken: Information on the inclusion of women in research related to implementation of Defending Women EO and OPM memo.
Status: In Progress

17. Review and terminate agency contracts that promote gender ideology
Action Taken: Women-related agency contracts were were fully terminated (6), updated activities (2), and modified language/data fields (39). Disseminate direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders. We engaged in consultation with IC staff to assist in making determinations about impact to certain contracts. We provided data related to actions taken on both executive orders back up to HHS, including cost savings data. As a result of a court order, OALM ensured compliance by providing the notice to all NIH contractor organizations by the stated deadline.
Status: Complete

18. Remove gender identifiers from agency forms - intramural individual development plans
Action Taken: NIH is removing the gender identifiers from internal OIR electronic development plan systems.
Status: In Progress

19. Review of pending awards and terminate any that promote or inculcate gender ideology
Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.
Status: In Progress

20. Review Notices of Funding Opportunity for Gender
Action Taken: NIH is currently reviewing all active and proposed Notices of Funding Opportunities and Notices of Special Interest to determine if they promote gender ideology and will take action as appropriate, including termination if needed.
Status: In Progress

21. Terminate Active Grants that Promote or Inculcate Gender Ideology
Action Taken: NIH is currently reviewing all active grants and supplements to determine if they promote gender ideology and will take action as appropriate.
Status: In Progress

22. Updating NIH Manual Chapter 1311 - Preventing and Addressing Harassment and Inappropriate Conduct
Action Taken: Updated NIH Manual Chapter 1311 to remove references to gender.
Status: Complete

23. Terminate trainings on gender ideology
Action Taken: The only thing identified was the Women in Leadership program, which doesn't meet this definition. Confirmed that we do not have any other trainings that inculcate or promote gender ideology.
Status: Complete

24. NIAID Grants Related to Gender - Additional Consideration
Action Taken: Correspondence about NIAID grants related to gender, surgery, hormone therapy.
Status: Additional Consideration

25. List of Women Related Protocols
Action Taken: NIH is reviewing all survey instruments, forms, protocols, and clinical guidelines to ensure compliance with EO 14168.
Status: In Progress

26. Terminate Special Interest Groups that Inclucate Gender
Action Taken: Employee resource groups or special emphasis programs that inculcate or promote gender ideology have been terminated.
Status: Complete

27. Withdraw Any Forms, Documents...That Inculcate or Promote Gender Ideology
Action Taken: NIH forms have been updated to remove gender identification.
Status: Complete

28. Terminate Active Contracts that Promote or Inculcate Gender Ideology
Action Taken: Review all agency contracts and terminate any that promote or inculcate gender ideology.
Status: In Progress

29. Report on training activities
Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but likely Defending Women, DEIA.
Status: Complete

30. Provide all updated or terminated reports that inculcate or promote gender ideology.
Action Taken: Updated or terminated reports that inculcate or promote gender ideology.
Status: Complete

31. Review of gender ideology positions and offices
Action Taken: Verification that Sexual and Gender Minority Office (SGMRO) has been disbanded and there are no current gender ideology job positions related to SGMRO
Status: Complete

32. Removal of Gender Related Outward Facing Media
Action Taken: Removed outward facing media (websites, social media accounts, etc.) that inculcates or promotes gender ideology. Implemented a freeze on external communication (websites, social media, press releases, listservs, individual public inquiries on sensitive health topics).
Status: Complete

33. Removal of webpages related to DEIA and gender ideology
Action Taken: Summary of OIR webpages removed in response to DEIA and gender EOs/memos.
Status: Complete

34. Review of women's health or sex as a biological variable activities - Feb 20
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

35. Review of women's health or sex as a biological variable activities - Feb 12
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

36. Review of women's health or sex as a biological variable activities - Feb 6
Action Taken: An initial review of current and planned 'women's health or sex as a biological variable' official agency activities identified 92 current or planned activities.
Status: Complete

37. Tribal Sovereignty - Additional Consideration
Action Taken: Information on tribal sovereignty related to implementation of Defending Women EO and OPM memo.
Status: Additional Consideration

38. Change gender to sex in NIH Databook
Action Taken: NIH Databook has updated about 16 reports that use "gender" or "women" in the title

and data.
Status: Complete

39. Ensure that intimate spaces designated for women, girls,or females (or for men, boys, or males) are designated by biological sex and not gender identity.
Action Taken: NIH has certified that gender neutral restrooms now use the terminology of men and women.
Status: Complete

40. Reporting on current or planned women's health and sex as a biological variable official agency activities
Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans , FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).
Status: Complete

41. Update Common Data Element (CDE) repository to address use of 'gender' and 'sex'
Action Taken: The Common Data Element (CDE) Repository contains a small number of CDEs that refer to gender; the National Library of Medicine (NLM) recommends adding a disclaimer to those items to clarify that "gender" should not be used to as a substitute for the data element "sex."
Status: Complete

42. Terminate intramural gender ideology programs
Action Taken: NIH is currently reviewing all intramural programs to determine if they promote gender ideology and will take action as appropriate, including termination if needed, by the 30-day deadline.
Status: In Progress

43. Terminate applications that include gender ideology
Action Taken: Applications to be funded that currently refer to "gender" in different contexts in abstracts and titles will be revised to exclude work related to gender ideology. If the grant is insufficient by excluding the gender ideology, it will be terminated.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB - OMB Memo: Freeze Funding

The memorandum from the Office of Management and Budget, dated January 27, 2025, directs Federal agencies to temporarily pause all financial assistance programs to align with President Donald J. Trump's priorities and executive orders, effective January 28, 2025, at 5:00 PM.

Implementation:

1. Purchase Card Reinstatements
Action Taken: Coordinated with leadership across the NIH Institutes and Centers to freeze 870 credit cards, reducing its open credit cards to only around 8% of its prior usage, to effectively reduce credit

card spend to the minimum emergency amount.
Status: Complete

2. Resume payments previously paused due to an EO and directives from the Office of Management and Budget (OMB).
Action Taken: As a result of multiple court orders, OALM ensured compliance by providing required legal notices to all NIH contractor organizations by the stated deadlines.OER outlined the priority order for releasing funds.
Status: Complete

3. NIH authorizes IC funding
Action Taken: ICs are authorized to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements 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.
Status: Complete

4. Temporary Restraining Order in National Council of Nonprofits et al. v. Office of Management and Budget et al.,
Action Taken: Restraining order that allows federal agencies to un-pause funding - OMB Memorandum M-25-13
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Initial Guidance Regarding DEIA Executive Orders

Pursuant to its authority under 5 U.S.C. § 1103(a)(1) and (a)(5), the U.S. Office of Personnel Management ("OPM") is providing the following initial guidance to agencies regarding the President's executive orders titled Ending Radical and Wasteful Government DEI Programs and Preferencing and Initial Rescissions of Harmful Executive Orders and Actions, which repeals Executive Order 14035, Diversity, Equity, Inclusion and Accessibility in the Federal Workforce.

Implementation:

1. Discussions with Tenure-Track Investigators Not on Administrative Leave
Action Taken: Ongoing meetings of the Deputy Director for and personnel in the Office of Intramural Research with each Tenure-track Investigator not currently on administrative leave to ensure compliance with no Federal funds going to DEI research.
Status: In Progress

2. Placed DEIA Employees on Administrative Leave
Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.
Status: Complete

3. Removal of DEIA Related Language from CY2025 Performance Plan
Action Taken: Updating Performance Plans by March 25, 2025.Review all remaining 2025 Performance Elements for Supervisory and Non-Supervisory employees and remove any DEIA related

language. Establish new 2025 Performance plans.
Status: Complete

4. Changes to webpages, flyers, posters related to DEIA, gender
Action Taken: Update nVistas (our foreign worker collection system and database) to ensure gender is changed to sex.Updates to research services posters (i.e. UNITE), flyers (Division of Personnel Security and Access Control), nVistas (foreign worker collection system and database), webpages (Employee Assistance Program) in response to EOs and memos on DEIA, gender.
Status: Complete

5. Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies.
Action Taken: Flagged for HHS the intersection of DEI directives and of the HHS and NIH Scientific Integrity Policies, Rescission of "any guidance, instruction, recommendation, or document issued by the IWG is withdrawn as no longer representative of governmental policy related to the Presidential Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking)." NIH is awaiting HHS direction as to whether HHS and NIH policy should be rescinded.
Status: In Progress

6. Termination of NIH Distinguished Scholars Program
Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research.
Status: Complete

7. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

8. Ensure that data analyses align with administration guidance
Action Taken: NIH is committed to Tribal Self-Determination and the long-term goal of maximizing tribal control over governmental institutions in tribal communities and recognizes that issues are best addressed in federal/Tribal partnership informed by Tribal traditions, values, and customs.
Status: In Progress

9. Integrate Compliance with Ending Radical and Wasteful Government DEI Programing Into the Entire Extramural Grant Process For All Grants and Contracts
Action Taken: Removed language regarding NIH's Interest in Diversity from Eligibility section of Notices of Funding Opportunities ("NOFOs"). Similar statements are being manually removed in other sections as they are identified. Removed language regarding "Plans for Enhancing Diversity (PEDP)" from multiple sections of NOFOs. Revised peer review processes to eliminate consideration of Plans for Enhancing Diversity (PEDP) across all opportunities, Diversity Plans in conference

grants, and Recruitment Plans to Enhance Diversity in training grants. Identified NOFOs that largely focus on DEI. These NOFOs were unpublished but then restored in response to the Temporary Restraining Order (TRO). These same 58 NOFOs were subsequently unpublished again from the NIH Guide and on Grants.gov at the direction of the Acting NIH Director on February 21, 2025. An additional 18 NOFOs were unpublished on the morning of February 24, 2025, in response to a separate subsequent directive from the Acting NIH Director. Development of a compliance plan by which adherence to Executive Orders – including Executive Orders on DEI – will be incorporated as a term and condition of award. Competing and non-competing awards are being released as required by the TRO. Drafted a term and condition of award for funding ICs to utilize on grants where DEI activities have been renegotiated out of the project. A public webpage is under development highlighting how NIH is implementing recent Executive Orders related to Grants and Applications.
Status: In Progress

10. Removal of DEI-Related Content from Microsoft 365
Action Taken: ICOs reviewed and verified their identified sites and content and ensured proper records management:
Status: Complete

11. Summary of DEIA Activities January 21 through February 6, 2025
Action Taken: This is a summary of DEIA activities January 21 through February 6, 2025.
Status: Additional Consideration

12. Compile a List of All DEI Websites and Equity Plans
Action Taken: List of all ICO DEI webpages and equity plans was compiled.
Status: Complete

13. Report on training activities
Action Taken: Report on all training activities across NIH, unclear which specific EO, memo, etc. but likely Defending Women, DEIA.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Deferred Resignation Program

Deferred Resignation Program

Implementation:

1. Contact Employees on Extended Leave about DRP
Action Taken: NIH contacted employees on extended leave to notify them to review to the Fork in the Road email or the OPM webpage.
Status: Complete

2. Provide Additional Guidance on Compliance with the Age Discrimination in Employment Act in the Implementation of DRP Agreements
Action Taken: OPM is providing additional guidance to agencies regarding implementation of the Deferred Resignation Program ("DRP"). Agencies should treat the DRP as an "exit incentive program" under section 7 of the Age Discrimination in Employment Act (ADEA). Accordingly, agencies should provide employees aged 40 and over with a supplemental notice containing

additional, agency-specific information necessary to comply with the OWBPA.
Status: Complete

3. Building Awareness of Guidance for Collective Bargaining Obligations to Deferred Resignation Offer
Action Taken: Agencies review all CBAs to determine whether provisions regarding resignation are covered by the CBA. To the extent any union proposals concerning employment conditions are not covered by a government-wide regulation or the CBA and the agency has discretion on implementation of certain aspects of the deferred resignation program, there may be some limited collective bargaining obligations. For example, negotiable proposals may include such matters as: Informing the employee of any benefits available or not available after resignation and of any applicable reemployment rights;
Status: Complete

4. Extension of Fork in the Road (DRP)
Action Taken: Employees who wanted to accept Deferred Resignation, replied to OPM's HR email address from their government email address with the word "resign".
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding RIFs of DEIA Offices

In accordance with that order, each agency, department, or commission head shall take action to terminate, to the maximum extent allowed by law, all DEI, DEIA, and "environmental justice" offices and positions within sixty days.

Implementation:
1. Placed DEIA Employees on Administrative Leave
Action Taken: 3/4/25: Ten employees were placed on administrative leave and five received probationary termination notices.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB - OPM Memo: Federal Civilian Hiring Freeze Guidance

This memorandum provides additional guidance regarding the freeze on the hiring of federal civilian employees as directed by the President on January 20, 2025, via Presidential Memorandum (PM) entitled "Hiring Freeze." This guidance clarifies immediate actions to be taken by Heads of executive departments and agencies to implement the PM and provides information on the types of exemptions authorized under this hiring freeze as well as instructions on how departments and agencies can request exemptions from the Office of Personnel Management (OPM) for critical situations where additional exemptions may be warranted.

Implementation:
1. Federal Civilian Hiring Freeze
Action Taken: Paused efforts to develop process for manage hiring freeze exceptions to wait further

information on the OPM Guidance on Agency RIF and Reorganization Plans. Canceled the Summer Internship Program for 2025.Freeze on the hiring of federal civilian employees as directed by the President on 1/20/2025.
Status: Complete

2. Not-To-Exceed Appointments Expiring through May 3
Action Taken: Each ICO to submit employee NTE date with position description and impact if extension is not approved.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Implementing President Trump's Executive Order titled, "Restoring Accountability To Policy-Influencing Positions Within the Federal Workforce"

On January 20, 2025, the President signed an Executive Order entitled, "Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce ("Restoring Accountability")." This Executive Order reinstates and amends Executive Order 13957 of October 21, 2020.1 It creates a new Schedule Policy/Career in the excepted service for positions that are of a confidential, policy-determining, policy-making, or policyadvocating character (policy-influencing positions) and filled by individuals not normally subject to replacement or change as a result of a Presidential transition. Such career positions will be rescheduled into Schedule Policy/Career and thereby exempted from the adverse action procedures set forth in chapter 75 of title 5 of the United States Code.

Implementation: N/A
Further Considerations: N/A

MEMO OPM, OMB - OPM Memo: Agency Return to Office Implementation Plans

The Office of Management and Budget (OMB) and the Office of Personnel Management (OPM) are issuing this memorandum to provide further guidance to agencies on implementation of the January 20, 2025, Presidential Memorandum (PM) Return to In-Person Work.

Implementation:
1. Action Updates for Return to In-Person Work
Action Taken: Summary of Office of Research Facilities-led activities related to return to In-Person work.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Revocation of Executive Order 14003

On January 20, 2025, President Trump signed Executive Order 14171 entitled, "Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce" ("Restoring Accountability"). Restoring Accountability revoked Executive Order 14003 of January 22, 2021 (Protecting the Federal Workforce).1 Executive Order 14003 rescinded several executive orders President Trump signed that regulated the federal workforce. The revocation of Executive Order 14003 order does not immediately reinstate those

orders.2 However, in light of Restoring Accountability, agencies should return to the policies of the first Trump Administration on discipline and unacceptable performance, as discussed below, as soon as practicable.

Implementation: N/A
Further Considerations: N/A

MEMO OPM - OPM Memo: Guidance Regarding Redesignating SES CIO Positions

Pursuant to its authority under 5 U.S.C. §§ 1103(a)(1), (5), and (7); 3132(b)(1) and 5 C.F.R. § 214.403, the U.S. Office of Personnel Management ("OPM") is providing guidance to agencies regarding agency Senior Executive Service ("SES") Chief Information Officer ("CIO") positions currently designated as career reserved. The role of agency CIOs has changed dramatically in recent years. No longer the station of impartial and apolitical technocrats, the modern agency CIO role demands policy-making and policy-determining capabilities across a range of controversial political topics. See 5 C.F.R. § 214.402(c)(1). In light of this new reality, OPM recommends that each agency with a CIO role classified as SES and designated as career reserved, send a request that OPM redesignate the position to "general" no later than Friday, February 14, 2025.

Implementation:

1. Redesignate SES CIO Positions
Action Taken: OPM recommends that each agency with a CIO role classified as SES and designated as career reserved, send a request that OPM redesignate the position to "general" no later than Friday, February 14, 2025.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Further Guidance Regarding Ending DEIA Offices Programs and Initiatives

This memo is providing additional guidance regarding the President's executive orders, including those titled, "Ending Radical and Wasteful Government DEI Programs and Preferencing," "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," and "Initial Rescissions of Harmful Executive Orders and Actions."

Implementation:

1. Termination of NIH Distinguished Scholars Program
Action Taken: Terminated the NIH Distinguished Scholars Program for tenured and tenure-track investigators, a program that was launched years ago to aid diversification of the biomedical workforce and mentoring for individuals otherwise not likely to pursue careers in biomedical research.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO HHS, Dorothy Fink, Acting Secretary - HHS Guidance: Immediate Pause on Issuing Documents and Public Communications

Presidential appointees need to review and approve any regulations, guidance documents and other public documents and communications (including social media).

Implementation:

1. Immediate Pause on Issuing Documents and Public Communications
Action Taken: Unless reviewed by a Presidential appointee, refrain from sending documents for publication to the Office of the Federal Register; refrain from publicly issuing any document or communication, refrain from participating in any public speaking engagements, refrain from issuing official correspondence to public officials regarding department regulations or policy.
Status: In Progress

2. Acquisition Guidance on Memo "Immediate Pause on Issuing Documents and Public Communications"
Action Taken: All acquisition workforce members must refrain from publicly issuing any document or participating in any communication until it has been reviewed and approved by a Presidential appointee.
Status: Complete

3. Resume Specific Communications Captured in Initial Communication Freeze
Action Taken: Ongoing changes to status will be updated as new information comes in. As of 2/26/25 - Center for Scientific Review (CSR) can begin sending notices incrementally to the Office of the Federal Register to advertise meetings of scientific review groups/study sections. Effective March 3 - all travel cards are frozen for 30 days and travel is on hold, including NIH scientists participating in public scientific conferences for the presentation of scientific data or for the purposes of learning about scientific data.
Status: In Progress

4. Identify high priority acquisition activities related to communications freeze
Action Taken: Data call to identify high priority acquisition activities related to communications pause.
Status: Complete

5. Information requested on Federal Advisory Committee Act (FACA) bodies, including estimated spending.
Action Taken: NIH reported information on Federal Advisory Committee Act (FACA) bodies, including estimated spending to HHS.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO HHS Acquisitions - HHS Guidance: Acquisition Guidance on Pause on Issuing Documents and Public Communications

Pausing communications with prospective vendors.

Implementation:

1. Identify high priority acquisition activities related to communications freeze
Action Taken: Data call to identify high priority acquisition activities related to communications pause.

Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OMB, Office of Information and Regulatory Affairs - OMB Guidance: Guidance on Implementing Section 3(e) of Executive Order 14168 in Accordance with the Paperwork Reduction Act and the Privacy Act

Specifies how agencies can implement Section 3(e) of EO 14168 in compliance with the PRA and the Privacy Act in a timely manner.

Implementation:

1. Guidance on Implementing Section 3(e) of Executive Order 14168 (Defending Women) in Accordance with the Paperwork Reduction Act and the Privacy Act
Action Taken: Guidance specifies how agencies can implement Section 3(e) of EO 14168 (Defending Women) in compliance with the Paperwork Reduction Act and the Privacy Act in a timely manner.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Agency RIF and Reorganization Plans Requested by Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative

President Trump required that "Agency Heads shall promptly undertake preparations to initiate large-scale reductions in force (RIFs), consistent with applicable law." President Trump also directed that, no later than March 13, 2025, agencies develop Agency Reorganization Plans. The U.S. Office of Management and Budget ("OMB") and the U.S. Office of Personnel Management ("OPM") now submit guidance on these Agency RIF and Reorganization Plans ("ARRP"), along with the instruction that such plans be submitted to OMB and OPM.

Implementation:

1. Submit Agency Reorganization Plans
Action Taken: 2/26/2025: Exec Sec sent email to department heads
Status: Not Started

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Presidential Memorandum Return to In-Person Work

Guidance from OPM

Implementation:

1. Return to Office Guidance
Action Taken: Guidance on the return to Office
Status: Complete

2. Approval to Proceed with Procurements to Support In-Person Work
Action Taken: Institutes and Centers are directed to carefully document, justify and support their minimal, immediate needs, in coordination with their acquisition staff. Reporting should include detailed itemizations of what funds are being obligated for.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Revised Guidance on Probationary Periods, Administrative Leave and Details

The U.S. Office of Personnel Management (OPM) is aware of recent litigation challenging the terminations of various probationary employees in different departments of the federal government. OPM is issuing this **revised guidance**, which revises and updates its earlier memo of January 20, 2025. The revised memorandum clarifies and confirms that OPM has not directed, and is not directing, your agency to take specific performance-based actions against probationary employees. Agencies have and continue to have ultimate decision-making authority over such personnel actions.

Implementation: N/A
Further Considerations: N/A

MEMO OPM - OPM Memo: Request for Agency Performance Data

To assist OPM in developing those metrics, no later than Friday, March 7, 2025, all agencies should submit data regarding their performance management plans and policies—including those contained in collective bargaining agreements—and identify any barriers to ensuring that 1) agency performance plans make meaningful distinctions based on relative employee performance and 2) the agency has the ability to swiftly terminate poor performing employees who cannot or will not improve.

Implementation:
1. Request for Agency Performance Management Data
Action Taken: Agencies should report to on employees with less than fully successful in the last three years.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance on Exempting Military Spouses and Foreign Service Spouses from Agency Return to Office Plans

Guidance on Exempting Military Spouses and Foreign Service Spouses from Agency Return to Office Plans

Implementation:
1. Guidance on Exempting Military and Foreign Service Spouses from Return to Work
Action Taken: Guidance on Exempting Military and Foreign Service Spouses from Return to Work
Status: Additional Consideration

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Maintaining the Integrity of the Career Senior Executive Service

Review and Reclassification of Positions: Each agency head should take the following actions:
1. Promptly identify all agency SES positions that were either (a) general designated SES positions on January 19, 2021; or (b) were general designated SES positions filled by noncareer appointments for a majority of the prior administration's tenure.
2. With respect to SES positions described in paragraph (1) that were designated as general and have been redesignated as career reserved, each agency head should promptly take all necessary actions to revert such positions back to the general designation, except with respect to any specific positions that the agency head requests should remain as career reserved positions pursuant to paragraph (3).
3. Within 45 days of the date of this memorandum each agency head should report the positions identified in the review prescribed by paragraph (1) (or those positions in the process of being redesignated), to the Office of Personnel Management ("OPM") at allocation-management@opm.govmailto:. If an agency head believes that the President's goals and priorities would be better served by keeping any such positions as career reserved positions, the agency head shall submit a request to retain the specific position as a designated career reserved position and explain the reasons therefore. Agency heads will send the request and explanation to OPM at allocation-management@opm.govmailto:.
4. Agencies shall coordinate with OPM to implement these actions, and request support including (a) identifying agency SES positions redesignated from general to career reserved after January, 19, 2021, (b) consultations regarding appropriate procedures for reassignments, pursuant to 5 U.S.C. 3395, and/or details, pursuant to 5 CFR 317.903, should an agency head determine such movement of a career executive is warranted to support the agency's mission , and, (c) any necessary guidance regarding implementation of paragraph (1), (2), and (3).

Implementation:
1. Maintaining the Integrity of the Career SES
Action Taken: Review and Reclassification of SES Positions
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding Redesignating CHCO Positions

OPM is providing guidance to agencies regarding agency Chief Human Capital Officer (CHCO) positions currently designated as career reserved Senior Executive Service (SES).

Implementation: N/A
Further Considerations: N/A

MEMO GSA - GSA Memo: Assistance with Terminating, Descoping, and Justifying Consulting Contracts

Review a list of GSA identified contracts and confirm if they are essential or non-essential.

Implementation:
1. Data Call: GSA Non-Essential Contracts

Action Taken: Coordinated with the NIH Director to established categories of spend that aligned with Presidential Appointee priorities and could continue, established a reporting system that categorizes how the NIH Acquisition Workforce is obligating funds within these categories.Established a contract approval process for routing individual requests for consideration of other procurement requirements to the NIH Director for mission critical needs that may not fit squarely within an approved spend category.Paused the issuance of any new Contracting Officer warrants or other Delegations of Procurement Authority.Coordinated the termination of 113 non-essential contract awards for an estimated cost savings of approximately $14.6M thus far. Additional reviews seeking further cost savings opportunities remain ongoing.Coordinated with HHS to provide data that will be publicly posted regarding NIH's justifications for certain contracts are mission critical.Developed a system to provide Department of Government Efficiency staff with weekly reports detailing all NIH contracting activities, and OALM advised NIH Dr. Memoli reviewed and approved the contracts in question.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Agency Reporting to OPM for FY 2024 Taxpayer-Funded Union Time Use

U.S. Office of Personnel Management (OPM) is requiring agencies subject to the Federal Service Labor-Management Relations Statute to administer the Statute in a manner consistent with the requirements of an effective and efficient government and, to authorize taxpayer-funded union time only in amounts that are reasonable, necessary, and in the public interest and to monitor its use to see that it is used efficiently.

Implementation:

1. Data Call: Reporting to OPM FY 2024 Taxpayer-Funded Union Time Use
Action Taken:
Status: In Progress

2. Data Call: Taxpayer-Funded Union Time Information
Action Taken:
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

MEMO OPM - OPM Memo: Guidance Regarding Redesignating CHCO Positions

To ensure accurate and consistent classification of CHCO positions, OPM recommends that each agency with a CHCO role designated career-reserved SES send a request that OPM convert the role to SES.

Implementation:

1. Data Call to Redesignate CHCO Positions
Action Taken:
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Coordinating Committee on Women's Health (CCWH) regarding Executive Order 14168

Description

Implementation:

1. Review of women's health or sex as a biological variable activities - Mar 3
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

2. Review of women's health or sex as a biological variable activities - Feb 20
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

3. Review of women's health or sex as a biological variable activities - Feb 12
Action Taken: A list of 'women's health or sex as a biological variable' official agency activities.
Status: Complete

4. Review of women's health or sex as a biological variable activities - Feb 6
Action Taken: An initial review of current and planned 'women's health or sex as a biological variable' official agency activities identified 92 current or planned activities.
Status: Complete

5. Reporting on current or planned women's health and sex as a biological variable official agency activities
Action Taken: Summary of current or planned women's health and sex as a biological variable official agency activities - NIH FACA Charters and Membership Balance Plans , FACA Committee Membership, and Electronic Research Administration (eRA) Committee Management Module (CMM).
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Secretarial Directive on DEI-Related Funding

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. The START document library includes additional information (memo)

Implementation:

1. Pause Approving Invoices or Completing Receiving for DEI Activities Performed by Contractors
Action Taken: In accordance with HHS guidance, OALM paused all payment of invoices related to DEI activities, and is coordinating with HHS on special review of these invoices prior to payment.
Status: Complete

2. Do Not Reinstate Contracts Terminated between Jan. 20th – Jan. 31st
Action Taken: Terminated 31 contracts focusing on DEI related activities impacting funding to the

vendor since January 20, 2025. Cost savings is roughly $6 million. The START document library includes additional information (email and spreadsheet).
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST OMB - GSA Assistance with Terminating, Descoping, and Justifying Consulting Contracts

In the enclosed spreadsheet, based on available procurement data, we have identified contracts your agency has awarded that may involve non-essential consulting. We ask that you complete the survey below for each contract. In the survey, indicate whether you plan to terminate the contract. If you do not plan to terminate a contract or descope requirement(s), write a one-sentence explanation in the space provided explaining why the consulting contract(s) is essential for your agency to fulfill its statutory purposes. In addition, please include the name of the person who represents that the consulting contract is essential. Finally, please use the survey to add any consulting contracts your agency has awarded that are not listed in the enclosed spreadsheet, and provide the information described above for each.

Implementation:

1. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

2. Assistance with Terminating, Descoping, and Justifying Consulting Contracts
Action Taken: Data call for consulting contracts to terminate, descope, justify complete. No data in START.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST OMB - GSA Identification of Contracts that may be Wasteful, Underutilized, Inefficiently Managed or Inconsistent with Presidential Directives

GSA is seeking ideas on new shared service opportunities, chances to reduce duplication, or otherwise drive better outcomes.
Identification of any Federal Acquisition Service (FAS) contracts that are inconsistent with recently adopted Presidential Directives.

Implementation:

1. Communicating a consolidated list of terminated NIH contracts
Action Taken: In response to a variety of EOs, memos, other requests the communication of a

consolidated list of terminated NIH contracts.Terminated 31 contracts that were providing DEI related services, for an estimated cost savings of around $6M in anticipated funding.Removed DEI activities from the broad scope of work that could be performed for 19 additional contracts.Disseminated direction and guidance to all NIH acquisition staff to terminate acquisitions that fell within the scope of the executive orders; Engaged in consultation with IC staff to assist in making determinations about impact to certain contracts.Provided cost savings data to HHS.Ensured compliance with court order by providing temporary restraining order notice to all NIH contractor organizations.
Status: Complete

2. Assistance with Terminating, Descoping, and Justifying Advertising and Marketing Contracts
Action Taken: Olga Acosta requested a due date extension to GSA for 3/21/2025.
Status: In Progress

3. GSA Identification of Contracts that may be Wasteful, Underutilized, Inefficiently Managed or Inconsistent with Presidential Directives
Action Taken: Identification of contracts that may be wasteful, underutilized, inefficiently managed or inconsistent with Presidential Directives.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Temporary Restraining Order - New York, et al. v. US. Office of Management and Budget (No. 25-cv-39) (Feb. 10, 2025, D. R.I.)

On 2/10/25k a district court issued a further order directing the Defendants, including the Department of Health and Human Services, to resume payments previously paused as a result of an executive order and directives from the Office of Management and Budget (0MB). In its order, the court addressed the argument that some continued pauses in funding were made pursuant to possible findings of fraud. The court rejected that argument and held that such funding pauses, viz., payment pauses made to "root out fraud," violate the plain text of the court's original temporary restraining order. Based on the Rhode Island District Court's order ofthis afternoon, and after consulting with the Department of Justice, this office provides the following guidance: All payments that are due under existing grants and contracts should be un-paused immediately.

Implementation:

1. Resume payments previously paused due to an EO and directives from the Office of Management and Budget (OMB).
Action Taken: As a result of multiple court orders, OALM ensured compliance by providing required legal notices to all NIH contractor organizations by the stated deadlines.OER outlined the priority order for releasing funds.
Status: Complete

2. NIH authorizes IC funding
Action Taken: ICs are authorized to proceed with issuing awards for all competing, non-competing continuation, and administrative supplements 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.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST HHS - Pausing FAIR Act

NIH leadership has decided to pause the FAIR Act Inventory activities until we receive further guidance from HHS.

Implementation:

1. Pausing of the FAIR Act Inventory activities
Action Taken: Due to an evolving administrative environment, NIH leadership has decided to pause the FAIR Act Inventory activities until we receive further guidance from HHS.
Status: Complete

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

REQUEST White House - Agency to Review all CFR Regulations and Guidance Documents

If a consultation is needed by DOJ, consultation request due 3/19/2025

Implementation:

1. Ensuring Lawful Governance and Implementing DOGE Regulatory Initiative
Action Taken: Development of policy and instructions underway to align with statue and EOAgency review of all regs in the CFR and all guidance docs.
Status: In Progress

Further Considerations: Discussions are ongoing regarding the timing of implementation of the compliance plans, once vetting and revisions are complete.

Research General Terms and Conditions
Agency Specific Requirements for the National Institutes of Health (NIH)
(April 8, 2021)

NIH Home Page: http://www.nih.gov/
NIH Office of Extramural Research Home Page: http://grants.nih.gov/grants/oer.htm
NIH Grants Policy Statement: http://grants.nih.gov/grants/policy/policy.htm
NIH Forms and Applications: http://grants.nih.gov/grants/forms.htm

I. NIH Implementation of the Research General Terms and Conditions

A. The Research General Terms and Conditions apply to all NIH grants and cooperative agreements with the exception of the automatic carryover provision found in 2 CFR § 200.308(e)(3)). Automatic carryover authority will be indicated on the Notice of Award (NoA) (See II.d below).

B. NIH Implementation of the Research General Terms and Conditions includes: 1) The Uniform Guidance as codified in 2 CFR §200; 2) conditions on activities and expenditure of funds in statutory requirements, such as those included in appropriations acts detailed at: http://grants.nih.gov/grants/policy/appropriations_info.htm; and 3) the NIH Grants Policy Statement.

C. For certain funding mechanisms, NIH implements streamlined requirements for progress report submission, the Notice of Award (NoA), and financial reporting. Known as the Streamlined Noncompeting Award Process (SNAP), NIH routinely applies SNAP to most Research Project (R-series) awards (except R35s, R41s, and R43s), and Career Development Awards (K-series). NIH grantees are expected to follow the SNAP process for those awards that are issued under the SNAP, as indicated on the NoA. Agency-specific requirements listed below will indicate where differences exist between SNAP and non-SNAP grants. Additional information on SNAP can be found in the NIHGPS, at 8.4.1.2, "Streamlined Noncompeting Award Process".

II. Prior Approval Requirements Not Included in or Modified from the Research General Terms & Conditions

a. Transfer of funds budgeted for participant support costs to other categories of expense (200.308(c)(5)): Waived, unless change in scope. For the purposes of Kirschstein NRSA programs, this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel in accordance with NRSA Regulations. Participant support costs are only allowable when identified in specific FOAs.

b. Subawarding, transferring or contracting out any work under a Federal award (200.308(c)(6)): NIH prior approval is required for the transfer of a significant part of the research or substantive programmatic effort only when the transfer represents a change of scope unless the transfer is to a foreign entity. If the transfer is to a foreign entity, prior approval must be obtained in order to complete the appropriate administrative assurances.

c. Initiate a one-time extension of the period of performance by up to 12 months (200.308(e)(2)): Recipients are required to notify NIH of their initiation of a one-time no-cost extension. Recipients are encouraged to use the No-Cost Extension Notification feature in the eRA Commons and can submit notifications up to the last day of the current end date, essentially waiving the 10-day requirement.

d. Carry forward unobligated balances to subsequent periods of performance (200.308(e)(3)): NIH prior approval may be required for carryover of unobligated balances on all P mechanisms except P01s; cooperative agreements (U's); Institutional National Research Service Awards (T's); Phase I SBIR & STTR (R43, R41); clinical trials (regardless of mechanism) and awards to individuals. The NIH Notice of Award will state whether prior approval is or is not required for carry over.

e. Subawards based on fixed amounts at any dollar amount, provided the subawards meet the requirements for fixed amount awards in 200.201(200.333): NIH prior approval is required in order for recipients to provide subawards based on fixed amounts (as defined in 2 CFR 200.45) to which the conditions in 2 CFR 200.201 apply.

f. Direct charge the salaries of administrative and clerical staff (200.413(c)(1)): NIH prior approval is not required to rebudget funds to direct charge the salaries of administrative and clerical staff if the following conditions are met: administrative or clerical services are integral to the project or activity; individuals involved can be specifically identified with the project or activity; the costs are not also recovered as indirect costs. The only time a prior approval request would need to be submitted is when additional funds are requested for such a position or the incurrence of such costs constitutes a change of scope.

g. Direct charge special arrangements and alterations costs incurred specifically for a Federal award (200.462(a)): NIH prior approval is required for Alterations and Renovations that exceed $500,000.

III. Allowable Direct Costs Aside from Those in 2 CFR 200

a. The allowability of direct costs not specifically covered by the provisions of 2 CFR 200, Subpart E shall be in accordance with the NIHGPS or the NIH Funding Opportunity Announcement published in the NIH Guide for Grants and Contracts, if more current.

IV. Non-Adoption of 2 CFR 200.240(a)(2) Termination Clause

a. NIH does not adopt 2 CFR § 200.240(a)(2), stating that the Federal awarding agency may terminate a Federal award if the award no longer effectuates the program goals or agency priorities. NIH derives and exercises discretionary decision-making related to program goals and priorities, separate and distinct from non-compliance, as described within the NIH GPS Section 2.4.4 Disposition of Applications.

V. Contact Information

a. Contact Information for Technical Matters

The NIH Scientific Program Official as identified on the Notice of Award is responsible for the scientific monitoring of the research.

b. Contact Information for Administrative Matters

The NIH Grants Management Officers/Specialist as identified on the Notice of Award is the official to be notified when required by the General Terms and Conditions.

c. Contact Information for Intellectual Property Matters

The NIH point of contact for intellectual property matters is:

Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration, NIH
6705 Rockledge Dr., Rm. 1136, MSC 7980
Bethesda, MD 20892-7980
Telephone: 301/435-1986

Inventions should be reported using Interagency Edison (located at http://www.iedison.gov/).

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining the NIH GPS. Interim changes to NIH grants policy will be published in the NIH Guide for Grants and Contracts. Each change will be described, including its applicability and effective date**.**

VI. Agency-Specific Requirements Related to Articles in The Research General Terms And Conditions

Part II Subpart B of the NIHGPS includes additional policy guidance as well as terms and conditions that vary from standard terms and conditions because of the type of grant, grantee, or grant-supported activity. These terms and conditions may apply in addition to or in lieu of those in the Research General Terms and Conditions. Each section of Part II Subpart B of the NIHGPS specifies how the coverage relates to Section II Subpart A of the NIHGPS, and consequently to the Research General Terms and Conditions.

Part II Subpart B includes:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities
- Ruth L. Kirschstein National Research Service Awards

- Research Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Institutions, International Organizations, and Domestic Grants with
- Foreign Components
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to For-Profit Organizations
- Research Patient Care Costs

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining the NIH GPS. Interim changes to NIH grants policy will be published in the NIH Guide for Grants and Contracts. Each change will be described, including its applicability and effective date

VII. Revised Budget Requirements

a. While a modified, streamlined, progress report is still a feature of grants awarded under the Streamlined Non-competing Award Process (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.
b. For non-SNAP awards, revised budget information should be submitted according to the instructions in Section H of the RPPR Instruction Guide.

VIII. Technical Reporting

NIH requires grantees to report on scientific progress using the Research Performance Progress Report (RPPR) module in eRA Commons. Annual progress reports submitted in any format other than the RPPR will not be processed by the NIH and will require resubmission through the RPPR.

As of January 1, 2017, NIH has replaced the Final Progress Report with the Final RPPR (F-RPPR). Generally, the format will be the same as the annual RPPR, making it easier for recipients to navigate through the F-RPPR based on familiarity with the existing format of the annual RPPR. Effective February 9, 2017, if the recipient organization has submitted a renewal application on or before the date by which an F-RPPR would be required for the current competitive segment, then submission of an "Interim-RPPR" via eRA Commons is now required. Based on this requirement, NIH has discontinued the policy for renewal applications whereby, “whether funded or not,” the progress report contained in the renewal application may serve in lieu of a separate final progress report.

IX. Financial Reporting

a. Generally, for SNAP awards, a Federal Financial Report (FFR) is required at the end of a competitive segment only. It must be submitted within 120 days after the end of the competitive segment and must report the cumulative support awarded for the entire competitive segment. An FFR must be submitted at this time whether or not a competing continuation award is made.

b. For non-SNAP awards, the FFR is required annually. 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 ends. The report must also cover any authorized extension in time of the budget period. For non-SNAP awards, the final FFR must be submitted within 120 days after the end of the competitive segment.

c. For grants eligible for automatic carryover, the FFR must specify the amount to be carried over to the next budget period. The notification must be provided under item 12, "Remarks," on the FFR.

d. If more frequent reporting is required, the NoA will specify both the frequency and due date.

FFRs must be submitted electronically to NIH using the FFR system located in the eRA Commons. Questions concerning specific financial matters should be directed to the Government Accounting Branch, 301-451-9210, or visit the Government Accounting web-page at https://ofm.od.nih.gov/Pages/Government-Accounts-Branch.aspx.

X. Incremental Funding Actions

A. SNAP:
1. Instructions for submitting SNAP progress reports are included in the RPPR Instruction Guide.
2. Career Development Awards that are issued under SNAP are to follow the RPPR instructions for SNAP and the CDA instructions of the RPRR at Section 7.1.
3. NIH will use the quarterly FFR cash transaction data submitted to the Payment Management System (PMS) to monitor the financial aspects of SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).

B. Non-SNAP
1. Instructions for submitting non-SNAP progress reports are included in the RPPR Instruction Guide.
2. Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards are to follow the specific training grant instructions of the RPPR at Section 7.4.

3. A FFR is required to be reported annually to NIH for non-SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).

***American Public Health Association, et al. v. National Institutes of Health, et al.*, No. 1:25-cv-10787-WGY**
Plaintiffs' List of Grants Impacted by the Directives (May 27, 2025)

This demonstrative is provided by Plaintiffs' counsel, pursuant to the Court's order on May 22, 2025, and to aid the Court in its understanding of the manner in which the Directives have been implemented as to Plaintiffs in *APHA, et al v. NIH, et al*. It contains information that Plaintiffs' counsel have been able to obtain and compile to date as to grant and program terminations. Inclusion of a grant or program on this list indicates that Plaintiffs' counsel have a good faith basis to believe that the *entire* grant or program and/or a supplement, parent, subpart, program or other award related to the grant or program has been terminated. Plaintiffs' counsel are continuing to analyze information regarding the grants that have been impacted by the Directives and will plan to provide supplemental lists as verification occurs. Plaintiffs reserve all rights to provide additional information regarding the impacts of the Directives on Plaintiffs and maintain that the resolution of Plaintiffs' claims—both as to liability and as to remedy—does not require the identification or individualized review of all impacted grants.

The Directives and terminations are unlawful in each of the following ways ("REASONS FOR EVERY GRANT"):

(1) They are in excess of statutory authority and contrary to statute (42 U.S.C. §§ 282(b)(4)–(6), 282(m)(1), 284(b)(1)(A), 284(b)(3)), in violation of 5 U.S.C. §§ 706(2)(A), 706(2)(C).

(2) They are contrary to regulation (45 C.F.R. § 75.372), in violation of 5 U.S.C. § 706(2)(A).

(3) They are arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).

(4) They violate the separation-of-powers principle and the Due Process Clause of the U.S. Constitution, and they accordingly violate 5 U.S.C. § 706(2)(B).

Project Number	Grant Title	Reason Termination is Illegal
1R61HD117134-01	Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01DA054236	Project SMART: Social media Anti-vaping Messages to Reduce ENDS Use Among Sexual and Gender Minority Teens	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01HD115551	Understanding multilevel predictors affecting family formation among sexual and gender minority couples	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD015256-05	Sexual orientation-related disparities in obstetrical and perinatal health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD015256-05S1	Sexual orientation-related disparities in obstetrical and perinatal health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01HD109320-02	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01HD109320-02S1	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD016384-03	An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R21MD018509-02	Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AA031213-02	The Impact of Minority Stress on Alcohol-Related Sexual Assault among Sexual Minority College Students: An Intersectional, Mixed-Methodological Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD017573-03	Sexual Assault Recovery Among Sexual Minority Women: A Longitudinal, Multi-Level Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R15AA030898-01A1	Reconstruction of an SGM-specific sexual violence peer support program (SSS+)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R34AA030662-01A1	An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R21MH136855-01	Over-the-Counter PrEP: Acceptability, Feasibility, and Potential Impact of Access without a Prescription (OFFSCRIPT)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R33TW011665-06	Development and Testing of a Mobile Application to Enhance HIV Prevention Cascade in Malaysian MSM	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3U24MD017250-04S1	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
5U24MD017250-04	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5T32MH019139-35	Behavioral Sciences Research in HIV Infection	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
3U01MD019398-03S1	Increasing financial and health equity among low income black youth and young adults - DEIA Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3U01MD019398-03S2	Increasing financial and health equity among low income black youth and young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3U01MD019398-03S3	Increasing financial and health equity among low income black youth and young adults - Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5U01MD019398	Increasing financial and health equity among low income black youth and young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01MD020284-01	Measures of structural stigmatization and discrimination for HIV research with Latine sexual and gender minorities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01AA029076-04S1	Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AA029076-04	Project Recognize: Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AA030017	A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R21AA031548-01A1	Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01AA031637-01A1	The Role of Local Structural Stigma in Alcohol Related Inequities among SGM Young Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1T32DA057926-01A1	Building an Interprofessional and diverse workforce in substance use and pain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1R01DA059240-01A1	Characterizing Intersectional Geospatial Stigma and Affirmation Landscapes and Their Influence on Black and Latino Bisexual Men At Risk for Substance Abuse and HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01DA059480-01A1	Elucidating minority stress influences on tobacco use at the intersection of sexual orientation and rurality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01DA060066-01	Combination of THC and CBD as a Novel Treatment for Co-Occurring Opioid Addiction and Chronic Pain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).

Project Number	Grant Title	Reason Termination is Illegal
1R01DA061661-01	Optimizing a Just-in-Time Adaptive Intervention to Increase Uptake of Chemsex Harm Reduction Services in MSM: A Micro-randomized Trial	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R21DA062591	Optimizing long-acting injectable PrEP strategies for sexual minority men who use methamphetamine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01AG063771-05S1	Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AG063771-05	Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
K12GM068524	San Diego IRACDA Scholars Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
3R01AG077934-03S1	Structural Racism and Discrimination in Sexual and Gender Minority Health Inequities - Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AG077934-03	Structural Racism and Discrimination in Older Men's Health Inequities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5UM2HD111102-03	Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R34MH126894	Making Universal, Free-of-Charge Antiretroviral Therapy Work for Sexual and Gender Minority Youth in Brazil	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH128049-04	Tcher, Take Charge: Increasing PrEP Awareness, Uptake, and Adherence Through Health Care Empowerment and Addressing Social Determinants of Health Among Racially Diverse Trans Women in the Deep South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R34MH129208-03	3T-Prevent: Piloting a multi-level, combination intervention strategy to expand HIV and bacterial STI prevention	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R24NS132283-01S1	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R24NS132283-01	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1RF1MH132360-01	Brief digital intervention to increase COVID-19 vaccination among individuals with anxiety or depression	See REASONS FOR EVERY GRANT.
5R01MH133821-02	The Socioecology of Sexual Minority Stigma: Data Harmonization to Address Confounding Bias and Investigate Cross-Level Mental Health Effects	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01MH138335-01	Bisexual adolescents' and young adults' risk for depression and suicidal ideation: Developmental trajectories, risk and protective factors, and underlying mechanisms	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination Is Illegal
5K23DK139454-02	Structural Racism as a "Third hit" on kidney outcomes of Black individuals with APOL1 risk alleles	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5T32GM141862-04	iBioSTeP: NIH G-RISE program at UC Merced	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1R01GM155395-01	Promoting Inclusive Excellence	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1K99GM155594-01	Characterization of the metastatic TIME by subcellular spatial profiling	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1U19AI171110-01	QCRG Pandemic Response Program	See REASONS FOR EVERY GRANT.
5R01AI172092-03	Enhanced COhort methods for HIV Research and Epidemiology (ENCORE) among transgender women in the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AI174862-03	Cabotegravir PrEP: Actionable Robust Evidence for Translation into Practice (CABARET)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31AI181431-01A1	Prevention of Chlamydia trachomatis infections: Evaluation of vaccination and post-exposure prophylactic antibiotic use as population-level strategies	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
R01CA265945	Testing effective methods to recruit sexual and gender minority cancer patients for cancer studies	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99NS129753-02	Cell type-specific mechanisms of history-dependent perceptual biases in sensory cortex	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
F31GM151838-02	Understanding the role of coiled-coil domains in regulating liquid-liquid phase separation of protein assemblies in cell division	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99AG086530-01	Alzheimer's Disease and Related Dementia Neuropathologies and Exposures to Traffic Pollution Mixtures	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
R25MH129290	Short Trainings on Methods for Recruiting, Sampling, and Counting Hard-to-Reach Populations: The H2R Training Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
DP2AI164315	One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31DA060046-01	Dopamine Projections to the Amygdala in Goal-Directed and Habit Learning	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
US4DA060049-02	Advancing Tobacco Regulatory Science to Reduce Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R24DA061190-01	PRIDE-CARES: Patient-Responsive Initiatives for Diverse Engagement – LGBTQ+ Community Action in Research to Eliminate Substance Use Disorder	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
1R01DA061345-01	Race & Place: The Impacts of Racial Inequity on Substance Use and HIV Outcomes in Los Angeles	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31DA061593-01	Community and big-data system approaches to identifying and understanding the health impact of xylazine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99DA062328-01	The role of valence encoding amygdala ensembles in avoidance behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
8K00DA062570-02	Investigating the role of microglia molecular rhythms in the nucleus accumbens in OUD	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
R01AG073440-03	Examining Health Comorbidities and Healthcare Utilization Disparities among Older Transgender and Cisgender Adults in the U.S.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01AG089099-01	Social Networks and Cognitive Health among Black and Latino sexual minority men in NJ	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01HD105655-04S1	Understanding and Supporting Reproductive Decisions Among Women with Developmental Disabilities that Affect Cognition	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5K12GM106996-09	IRACDA at UCLA	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5U01HD108738-03	Harnessing the power of text messaging to reduce HIV incidence in adolescent males across the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R21HD109536	Evaluating Teen-Parent Dynamics in Adolescent COVID-19 Vaccine Acceptance and Uptake	See REASONS FOR EVERY GRANT.
1R01HD110428-01A1	Modeling Adolescent Health Care Decision-Making for Vaccines: A Community- Based Participatory Approach	See REASONS FOR EVERY GRANT.
1R21HD110617-01A1	Development and Initial Trial of Brief Interventions to Help Parents of Stigmatized Youth Reduce Distress and Strengthen Attachment	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01MH115765	A couples-based approach to HIV prevention for transgender women and their male partners	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01HD115985-01	The California Abundant Birth Project Evaluation: Advancing Birth Equity through Guaranteed Income for Pregnant People	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R25HD116367	Restoring equity to measuring and preventing perinatal intimate partner violence (Remap-IPV)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3P30AI117943-10S1	Third Coast Center for AIDS Research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH118245-05	Biopsychosocial mechanisms underlying internalizing psychopathology in a prospective, population-based cohort of sexual minority young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
R25MH119858	SHINE Strong: Building the pipeline of HIV behavioral scientists with expertise in trans population health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5R33MH120236-04	Suicide Prevention for Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH121194-04	Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99NS126639/R00NS126639	Mitochondrial fidelity in mammalian neurons	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5R25MH126703-05	Pipeline to Graduate Education and Careers in Behavioral and Social Science Research for URM Undergraduates: Addressing HIV in Sexual and Gender Minority Communities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5T32MH126772-04	Culturally-focused HIV Advancements through the Next Generation for Equity (CHANGE) Training Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5R21MH128114-02	Strengthening the HIV care continuum for transgender women living with HIV in Malaysia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH128130-04	STI Response and Recommendations Under PrEP (STIRRUP)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01MH128729-03S2	Project STRIVE (STudents Rising above) - Offsetting the health and mental health costs of resilience	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
7R01MH129175-03	Strategies to Prevent HIV Acquisition Among Transgender MSM in the US	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R34MH129187	Brothers building brothers by breaking barriers (B6): A resilience-focused intervention for young Black gay and bisexual men living with HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R34MH129189-03	Data-driven, peer-led messaging using social media influencers to increase PrEP awareness and uptake among transgender women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01MH129285	A multi-level approach to improve HIV prevention and care for transgender women of color	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH130375-02	A longitudinal and experience sampling investigation of rejection sensitivity and its role in sexual minority adolescents' mental health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R34MH132405-01	MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MH132415	Understanding the Regional Ecology of a Future HIV Vaccine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
5R01MH133543-02	Implementing sustainable evidence-based mental healthcare in low-resource community settings nationwide to advance mental health equity for sexual and gender minority individuals	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R61MH133710-01A1	Targeting Minority Stressors to Improve Eating Disorder Symptoms in Sexual Minority Individuals with Eating Disorders	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
4R00DK133804	Utilizing a human stem cell model of the esophagus to understand racial disparities during injury repair	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1K23MH134111-01	Using youth-engaged methods to develop and evaluate a measure for disordered eating behaviors in transgender and gender-diverse youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31MH134720-01A1	Understanding Patient Level Implementation Determinants Related to Long-acting Injectable HIV Pre-Exposure Prophylaxis among Young Men Who Have Sex with Men Living in Rural Areas	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5R01MH134721-02	A randomized clinical trial of client-centered care coordination to improve pre-exposure prophylaxis use for Black men who have sex with men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R21DK134815-01A1	Transforming motivational interviewing into a computable model for automated patient diabetic counseling.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R34MH134912-01A1	Youth Empowerment and Safety Intervention for Systems-Involved Sexual and Gender Minority Youth at Risk of Suicide	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99MH135061-02	Oxytocin receptor signaling modulates social attachment via hippocampal CA2/3 function	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
3R01DK135099-02S1	Diversity Supplement for: Impact of a Healthy Checkout Policy on Healthfulness of Grocery Environments and Sales	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
R36MH135619	Transcriptomic contributions to the development and evolution of the human cerebral cortex	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5F32MH135634-02	The psychological underpinnings of gender disparities in adolescent mental health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
R01MH135738	Know your status: A cluster randomized controlled trial comparing healer-initiated HIV counseling and testing to standard of care in rural South Africa	See REASONS FOR EVERY GRANT.
5F99NS135767-02	Neural basis of movement in health and disease	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99MH135993-01	Neural circuit dynamics of spatial reward memory	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).

Project Number	Grant Title	Reason Termination is Illegal
1R21DK136084-01A1	Mobile pop-up units for diabetes prevention among Hispanics in rural Indiana	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31MH136729-01A1	Determining the role of discrimination in clinical presentation and treatment response among sexual minority people with OCD: A machine learning approach	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5U01DK137259-02	Renal transplant Equity through Partnership And Structural Transformation (REPAST)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1U01DK137262	CommunityRx - Chronic Kidney Disease (CRx-CKD): An EMR-integrated community resources referral intervention to address structural racism and kidney health disparities in rural North Carolina	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5U01DK137269-02	Mitigating the Effects of Structural Racism on Chronic Kidney Disease Disparities among African Americans	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5U01DK137272-02	NAVIGATE Kidney: A Multi-Level Intervention to Reduce Kidney Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
K23MH137389-01	ALIVE: Development and feasibility of a psychosocial intervention for sexual and gender minority autistic adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o* (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1R01MH137695-01	Measuring and Mapping Trajectories of Risk and Resilience for Suicidal Thoughts and Behaviors in Sexual and Gender Minority Preteens	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R34MH137753-01	Developing and pilot testing an eHealth decision support tool for young trans women to improve informed decision making about PrEP	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01MH140023-01	Mental Health Effects of Marriage Policy: Evidence from Linked Administrative Data in New Zealand	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R00GM140269-04	Evolution of Cargo Transport	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99DK140511-01	Fcγ Receptor-Mediated Pharmacogenomics of Antibody Therapies in Type 1 Diabetes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5T34GM141986-04	Maximizing Access to Research Careers (MARC) at University of Hawaii at Manoa	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM146016/4R00GM146016-03	Regulation of zinc-dependent lysosome morphological restructuring, zinc trafficking and low zinc homeostasis in C. elegans and human model systems	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
K99GM146243-01	The genetic control of neuronal number and behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM147825-02	Understanding and rewiring cellular behavior with synthetic biology approaches	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).

Project Number	Grant Title	Reason Termination Is Illegal
5K99GM148819-02	Elucidating the epigenetic regulation of extracellular matrix and virus-induced fibroblast activation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5R01HL149778-05	Cardiovascular Health of Sexual and Gender Minorities in the Hispanic Community Health Study/Study of Latinos (SGM HCHS/SOL)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
K99GM151467-02	Nuclear and chromatin aberrations during non-apoptotic cell death in C. elegans and mammals	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
K99GM151473	Characterizing the role of tumor suppressor phase separation and chromatin organization in maintaining genomic integrity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM152834-02/4R00GM152834-03	Regulation of oxidative stress signaling by tyrosine phosphorylation of antioxidant enzymes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM152835-02	Testing the functional consequences of rapid centromeric DNA and protein evolution	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99GM154059-01A1	RNA and genome regionalization in giant single cells: implications for cellular patterning	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
K99GM154061	Investigating UPF3 paralog function in Nonsense-Mediated mRNA Decay and Genetic Compensation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
3R01AI155739-04S1	Diversity Supplement - Environmental surveillance of albendazole resistance markers in human infective helminths using dual amplicon metabarcoding	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99GM157463-01	Building Dendrite Architecture via Microtubule Nucleation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
K99GM157504	Understanding eukaryotic proteasome assembly regulation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99GM159354-01A1	Metabolic regulation of pancreatic metaplasia and neoplasia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5R01HL160326-05	Stigma and the non-communicable disease syndemic in aging HIV positive and HIV negative MSM	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3P01AI165075-01S1	Broad neutralization of pandemic threat cor	See REASONS FOR EVERY GRANT.
R01AI169239	Uptake, safety and effectiveness of COVID-19 Vaccines during Pregnancy	See REASONS FOR EVERY GRANT.
5K99HL169908-02	Examining the Role of Structural Factors in Racial and Ethnic Disparities in Cardiovascular Disease	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5K99AI173544-02	Improving phage-based medicine with immunoengineering	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99HL173668-01	Resistance Exercise in the Prevention and Treatment of Heart Failure with Preserved Ejection Fraction (HFpEF)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).

Project Number	Grant Title	Reason Termination is Illegal
1K99AI182451-01	Molecular understanding of maternal humoral responses to pregnancy	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
R01CA237670	Project RESIST: Increasing Resistance to Tobacco Marketing Among Young Adult Sexual Minority Women Using the Inoculation Message Approaches	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1U54CA267730-01	Fostering Institutional Resources for Science Transformation: The FLORIDA-FIRST Health-science Brigade	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5U54CA267776-04	NIH FIRST Cohort Cluster Hiring Initiative at Icahn School of Medicine at Mount Sinai	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o* (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1UC2CA293786	ComPASS Health Equity Research Hub at Yale	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
U54MD007598	Accelerating Excellence in Translational Science (AXIS)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o(* b)(2), 285t-1(a)(b), and/or 288(a)(4).
5T37MD008636-10	Transdisciplinary Health Disparities Research Training for Native Hawaiians and Pacific Students	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5D43TW012274-03	Integrated Networks of Scholars in Global Health Research Training (INSIGHT)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1R01HG013145-01	Trans/Forming Genomics: Guidance for Research Involving Transgender and Gender Diverse People	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD013495-05	Health disparities, stress pathways, and stress-related comorbidities among MSM living with HIV	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD016864-03	K-VAC: Kentucky Vaccinating Appalachian Communities	See REASONS FOR EVERY GRANT.
R01MD016880-03	Increasing COVID-19 vaccine uptake among Latinos through a targeted clinical and community-behavioral intervention	See REASONS FOR EVERY GRANT.
4R00MD016964-03	Comprehensive computational analysis of genetic and regulatory differences between individuals with African and European ancestries across four brain regions	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o(* b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
P50MD017349	Chicago Chronic Condition Equity Network	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD017364-03	REDES: a peer network and mobile health (mHealth) enhanced CHW model to maximize COVID-19 vaccination among low income Latinos	See REASONS FOR EVERY GRANT.
1K99MD018451-01A1	Advancing Indigenous Cancer Health Equity through a Community-Centered Framework	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o(* b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
R01MD018459	Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination Is Illegal
R01MD018523	A Multilevel, Multiphase Optimization Strategy for PrEP: Patients and Providers in Primary Care	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD018679-02	Understanding the Role of Structural Oppression for Suicide Risk among Black Sexual and Gender Minority Adolescents and Young Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99MD019060	A Digital Health Intervention to Increase Condom Use Among Adolescent Sexual Minority Males	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1K99MD019292-01	A Multilevel Social Capital Approach to Address Cervical Cancer Screening and Follow Up Delays among Latinas in Safety-Net Settings	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
R21MD019345-01A1	Ecological momentary assessment of daily minority stressors and cannabis and tobacco co-use among sexual minority adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1P50MD019475-01	The Institute for Health Equity Research Catalyst Center	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1R21MD019829-01	The Roles of Parental Mental Health and Help-Seeking: Utilizing a Family Systems Approach to Upstream Suicide Prevention for Sexual Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31MD019996-01	Advancing Perinatal Health Equity through a Community-engaged Model of Healthcare Services	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1F31MD020261-01	Understanding the Macrosocial Drivers of Cardiovascular Health in the Rural South	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5R01NR020309-04	Harnessing the power of technology to develop a population-based HIV prevention program for trans girls	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99DC020570-02/4R00DC020570-03	Identifying neural circuits that support effortful listening	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o*(b)(2), 285t-1(a)(b), and/or 288(a)(4).
5R01NR020846-02	#TranscendentHealth - Adapting an LGB+ inclusive teen pregnancy prevention program for transgender boys	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1U24NR021014-02	Advancing Health Equity Through Innovative Community Capacity Building, Data Science & Delivering Community-Centered Structural Interventions & Outcomes: Drexel's ComPASS Coordinating Center (C3)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
OT2OD025276	PRIDEnet for the All of Us Research Program	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AA029044-04	Intersectional Approaches to Population-Level Health Research: Role of HIV Risk and Mental Health in Alcohol Use Disparities among Diverse Sexual Minority Youth	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
5R01AA029088-03	A unified protocol to address sexual minority women's minority stress, mental health and hazardous drinking	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
4R00AA030601-03	Stigma, Romantic Relationships, and Alcohol Use Among Transgender and Nonbinary Young Adults	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5F31AA030722-02	Examining differential effects of state equality-promoting policies on harmful alcohol use among sexual and gender minority adults in the U.S.: an econometrics approach for causal inference	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
1R15AA030898-01A1	Reconstruction of a SGM-specific sexual violence peer support program (SSS+)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1F31AA031420-01A1	Examining Proximal Associations between Minority Stress, PTSD Symptoms, and Alcohol Use among Bi+ College Students with Trauma Histories	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5R01ES034303-03	Research Employing Environmental Systems and Occupational Health Policy Analyses to Interrupt the Impact of Structural Racism on Agricultural Workers and Their Respiratory Health (RESPIRAR)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
OT2OD035659-01	Macro-level Health Considerations of Community and Criminal Justice System Relationships in North Texas	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
1K99EB036553-01	AN ADAPTIVE FRAMEWORK TO SYNTHESIZE AND RECONFIGURE BACTERIAL VIRUSES (PHAGES) TO COUNTER ANTIBIOTIC RESISTANCE	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283*o*(b)(2), 285t-1(a)(b), and/or 288(a)(4).
5U01DA036939-10	Multilevel Influences on HIV and Substance Use in a YMSM cohort	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3P2CHD041023-24S1	"Minnesota Population Center" (Note: this is a Diversity Supplement of the Parent Grant)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
3P30AI050409-26S1	Center for AIDS Research at Emory University	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01DA052016	Substance use and DNA methylation at the intersection of sex and gender	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R03DA052651	Improving Sexual Minority Health: Differences in Substance Use, Substance Use Treatment, and Associated Chronic Diseases among Rural versus Urban Populations	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01DA055673-03S1	Supplement entitled, "Exploring the accessibility, acceptability, and utilization of a community-based harm reduction vending machine among persons with limited opportunity structures."	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283*o*(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
R01DA056235	Structural Influences on Methamphetamine Use among Black Gay and Bisexual Men in Atlanta	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
5R01DA056287-02	Comparative- and cost-effectiveness research determining the optimal intervention for advancing transgender women living with HIV to full viral suppression	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01DA056888-03	Optimizing PrEP Implementation and Cost-effectiveness among Sexual and Gender Minority Individuals with a Substance Use Disorder	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01DA058642-02	Testing a multistage model of risk factors for cannabis use utilizing a measurement burst design among sexual minority women, sexual minority gender diverse individuals, and heterosexual women	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01MD012793-05	Advancing novel methods to measure and analyze multiple types of discrimination for population health research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3R01MD015165-04S1	Multilevel Physical Activity Intervention for Low Income Public Housing Residents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5T32MH020004	Research Training in Late-Life NeuroPsychia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1R01NR020583-01	Ending the HIV Epidemic with Equity: An All-facility Intervention to Reduce Structural Racism and Discrimination and Its Impact on Patient and Healthcare Staff Wellbeing	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01NR021098	Evaluating the Implementation and De-Implementation of Pandemic Era SNAP Expansion Policies on Diet and Health: A Mixed Methods Project	See REASONS FOR EVERY GRANT.
1F31NR021239-01	Personal Healthcare Networks of Transgender and Gender-Diverse Adults After Gender-Affirming Surgery	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R00AA028049	A mixed-methods approach to understanding stress and hazardous drinking among same-sex female couples	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
T32DA031099-13	Substance Abuse Epidemiology Training Program (SAETP) at Columbia University	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K01DE033040-01A1	Developmental mechanisms in the formation and function of sensory-motor circuits responsible for suckling and mastication.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
U01OD033248	TransHealthGUIDE: Transforming Health for Gender-Diverse Youth Using Interventions to Drive Equity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3OT2OD035592	Proyecto Juntos	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5UM1AI068619-19	Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation for Transgender Women in the Americas: A Vanguard Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
3R01AG075734	Training the Long-Term Services and Supports Dementia Care Workforce in Provision of Care to Sexual and Gender Minority Residents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5UM2HD111076-03	Operations and Collaborations Center - Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Operations and Collaborations Center (UM2 Clinical Trial Optional)	See REASONS FOR EVERY GRANT.
1K23HD112599-01A1	Caregiver decision making for seasonal respiratory vaccines for children	See REASONS FOR EVERY GRANT.
1R21HD116080-01	Confidentiality in use of health insurance coverage for reproductive health services	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
R01MH130007	Understanding the Interplay between Parent and Child Contributions in Parent-Child Anxiety Transmission	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5K99MH133994-02	Computational and neurodevelopmental mechanisms of memory-guided decision-making	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1R36MH135609-01	An intersectional approach to transgender and/or nonbinary college student mental health: The role of gender identity, race/ethnicity, socioeconomic status, and campus policy	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5K99NS135649-02	Computational Methods for Precise Holographic Control and Mapping of Neural Circuits	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM144750-02	Dynamic mechanisms of transcriptional coactivator function in Notch signaling	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99GM148723-02	Stress tolerant annual killifish: a new model for the cellular stress response	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1R15GM152943-01	"Mathematical Modeling and Scientific Computing for Infectious Disease Research."	See REASONS FOR EVERY GRANT.
5K99GM153720-02	Dissecting the synaptic and circuit mechanisms underlying olfactory-driven social behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99GM154060-01	TULP3 integrates essential ciliary functions	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
1K99GM157508-01	Unraveling the role of molecular capacitors that obscure cryptic genetic variation in Astyanax mexicanus during the evolution of eye loss	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5K99HL166700-02	Investigating relationships between naturalistic light exposure and sleep	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5P01AI168148-02	Leptospiral-Phagocyte Dynamics in Leptospirosis	See REASONS FOR EVERY GRANT.
1U19AI171401-01	Metropolitan AntiViral Drug Accelerator	See REASONS FOR EVERY GRANT.
R01CA251478	Local Flavor Policies to enhance equity in tobacco	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.

Project Number	Grant Title	Reason Termination is Illegal
R34CA283483-02	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa	See REASONS FOR EVERY GRANT.
5K99MD018629-02	Racism-related stress and birth outcomes among Latinas: New tools for maximizing conceptual and methodological validity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
5K01AG056669-05	The Epidemiology of Alzheimer's Disease and Related Dementias in Sexual and Gender Minority Older Adults: Identifying Risk and Protective Factors	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R24AG066599-03	Building Community and Research Engagement among Sexual and Gender Minority Older Adults at Risk for Alzheimer's Disease and Related Dementias	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01AG083177-02	Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons living with Alzheimer's Disease and Related Dementias	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
2T32GM135742-06	UCSC IMSD	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
5R01MD018250-03	Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5R01CA274564-03	Impact of Allostatic Load and Neighborhood Contextual Factors on Breast Cancer in the Women's Health Initiative	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

American Public Health Association, et al. v. National Institutes of Health, et al.
No. 1:25-cv-10787-WGY
Plaintiffs' Supplemental List of Grants Impacted by the Directives (June 13, 2025)

This demonstrative is provided by Plaintiffs' counsel, as a supplement to the original demonstrative provided on May 27, 2025 pursuant to the Court's order on May 22, 2025, to aid the Court in its understanding of the manner in which the Directives have been implemented as to Plaintiffs in *APHA, et al v. NIH, et al*. It contains information that Plaintiffs' counsel have been able to obtain and compile to date as to grant and program terminations. The terminations that were included in Plaintiffs' May 27, 2025 submission are contained in rows 1–234. Rows 235–367 contain the supplemental submissions. Inclusion of a grant or program on this list indicates that Plaintiffs' counsel have a good faith basis to believe that the entire grant or program and/or a supplement, parent, subpart, program or other award related to the grant or program has been terminated.

This list likely does not represent the complete universe of terminated grants and grant programs impacting Plaintiffs. Plaintiffs reserve all rights to provide additional information regarding the impacts of the Directives on Plaintiffs and maintain that the resolution of Plaintiffs' claims—both as to liability and as to remedy—does not require the identification or individualized review of all impacted grants.

The Directives and terminations are unlawful in each of the following ways ("REASONS FOR EVERY GRANT"):

(1) They are in excess of statutory authority and contrary to statute (42 U.S.C. §§ 282(b)(4)–(6), 282(m)(1), 284(b)(1)(A), 284(b)(3)), in violation of 5 U.S.C. §§ 706(2)(A), 706(2)(C).

(2) They are contrary to regulation (45 C.F.R. § 75.372), in violation of 5 U.S.C. § 706(2)(A).

(3) They are arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).

(4) They violate the separation-of-powers principle and the Due Process Clause of the U.S. Constitution, and they accordingly violate 5 U.S.C. § 706(2)(B).

Row Number	Project Number	Grant Title	Reason Termination Is Illegal
1	1R61HD117134-01	Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
2	R01DA054236	Project SMART: Social media Anti-vaping Messages to Reduce ENDS Use Among Sexual and Gender Minority Teens	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
3	R01HD115551	Understanding multilevel predictors affecting family formation among sexual and gender minority couples	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
4	5R01MD015256-05	Sexual orientation-related disparities in obstetrical and perinatal health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
5	5R01MD015256-05S1	Sexual orientation-related disparities in obstetrical and perinatal health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
6	5R01HD109320-02	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
7	3R01HD109320-02S1	Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
8	5R01MD016384-03	An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
9	5R21MD018509-02	Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
10	5R01AA031213-02	The Impact of Minority Stress on Alcohol-Related Sexual Assault among Sexual Minority College Students: An Intersectional, Mixed-Methodological Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
11	5R01MD017573-03	Sexual Assault Recovery Among Sexual Minority Women: A Longitudinal, Multi-Level Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
12	1R15AA030898-01A1	Reconstruction of an SGM-specific sexual violence peer support program (SSS+)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
13	1R34AA030662-01A1	An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
14	1R21MH136855-01	Over-the-Counter PrEP: Acceptability, Feasibility, and Potential Impact of Access without a Prescription (OFFSCRIPT)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
15	5R33TW011665-06	Development and Testing of a Mobile Application to Enhance HIV Prevention Cascade in Malaysian MSM	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
16	3U24MD017250-04S1	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
17	5U24MD017250-04	Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
18	5T32MH019139-35	Behavioral Sciences Research in HIV Infection	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
19	3U01MD019398-03S1	Increasing financial and health equity among low income black youth and young adults - DEIA Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
20	3U01MD019398-03S2	Increasing financial and health equity among low income black youth and young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
21	3U01MD019398-03S3	Increasing financial and health equity among low income black youth and young adults - Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
22	5U01MD019398	Increasing financial and health equity among low income black youth and young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

23	1R01MD020284-01	Measures of structural stigmatization and discrimination for HIV research with Latine sexual and gender minorities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
24	3R01AA029076-04S1	Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
25	5R01AA029076-04	Project Recognize: Improving Measurement of Alcohol Use and Other Disparities by Sex, Sexual Orientation, and Gender Identity through Community Engagement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
26	5R01AA030017	A Randomized Controlled Trial of a Game-Based Intervention to Reduce Alcohol Use among Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
27	1R21AA031548-01A1	Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
28	1R01AA031637-01A1	The Role of Local Structural Stigma in Alcohol Related Inequities among SGM Young Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
29	1T32DA057926-01A1	Building an interprofessional and diverse workforce in substance use and pain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
30	1R01DA059240-01A1	Characterizing Intersectional Geospatial Stigma and Affirmation Landscapes and Their Influence on Black and Latino Bisexual Men At Risk for Substance Abuse and HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
31	R01DA059480-01A1	Elucidating minority stress influences on tobacco use at the intersection of sexual orientation and rurality	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
32	1R01DA060066-01	Combination of THC and CBD as a Novel Treatment for Co-Occurring Opioid Addiction and Chronic Pain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
33	1R01DA061661-01	Optimizing a Just-in-Time Adaptive Intervention to Increase Uptake of Chemsex Harm Reduction Services in MSM: A Micro-randomized Trial	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
34	R21DA062591	Optimizing long-acting injectable PrEP strategies for sexual minority men who use methamphetamine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
35	3R01AG063771-05S1	Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
36	5R01AG063771-05	Effects of Social Networks and Policy Context on Health among Older Sexual and Gender Minorities in the US South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
37	K12GM068524	San Diego IRACDA Scholars Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
38	3R01AG077934-03S1	Structural Racism and Discrimination in Sexual and Gender Minority Health Inequities - Supplement	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
39	5R01AG077934-03	Structural Racism and Discrimination in Older Men's Health Inequities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
40	5UM2HD111102-03	Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
41	R34MH126894	Making Universal, Free-of-Charge Antiretroviral Therapy Work for Sexual and Gender Minority Youth in Brazil	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
42	5R01MH128049-04	Tcher, Take Charge: Increasing PrEP Awareness, Uptake, and Adherence Through Health Care Empowerment and Addressing Social Determinants of Health Among Racially Diverse Trans Women in the Deep South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
43	5R34MH129208-03	3T-Prevent: Piloting a multi-level, combination intervention strategy to expand HIV and bacterial STI prevention	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
44	3R24NS132283-01S1	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
45	1R24NS132283-01	PURPOSE: Positively Uniting Researchers of Pain to Opine, Synthesize, and Engage	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

46	1RF1MH132360-01	Brief digital intervention to increase COVID-19 vaccination among individuals with anxiety or depression	See REASONS FOR EVERY GRANT.
47	5R01MH133821-02	The Socioecology of Sexual Minority Stigma: Data Harmonization to Address Confounding Bias and Investigate Cross-Level Mental Health Effects	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
48	1R01MH138335-01	Bisexual adolescents' and young adults' risk for depression and suicidal ideation: Developmental trajectories, risk and protective factors, and underlying mechanisms	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
49	5K23DK139454-02	Structural Racism as a "Third hit" on kidney outcomes of Black individuals with APOL1 risk alletes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
50	5T32GM141862-04	IBioSTeP: NIH G-RISE program at UC Merced	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
51	1R01GM155395-01	Promoting Inclusive Excellence	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
52	1K99GM155594-01	Characterization of the metastatic TIME by subcellular spatial profiling	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
53	1U19AI171110-01	QCRG Pandemic Response Program	See REASONS FOR EVERY GRANT.
54	5R01AI172092-03	Enhanced COhort methods for HIV Research and Epidemiology (ENCORE) among transgender women in the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
55	5R01AI174862-03	Cabotegravir PrEP: Actionable Robust Evidence for Translation into Practice (CABARET)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
56	1F31AI161431-01A1	Prevention of Chlamydia trachomatis infections: Evaluation of vaccination and post-exposure prophylactic antibiotic use as population-level strategies	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
57	R01CA265945	Testing effective methods to recruit sexual and gender minority cancer patients for cancer studies	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
58	5K99NS129753-02	Cell type-specific mechanisms of history-dependent perceptual biases in sensory cortex	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
59	F31GM151838-02	Understanding the role of coiled-coil domains in regulating liquid-liquid phase separation of protein assemblies in cell division	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
60	1K99AG086530-01	Alzheimer's Disease and Related Dementia Neuropathologies and Exposures to Traffic Pollution Mixtures	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
61	R25MH129290	Short Trainings on Methods for Recruiting, Sampling, and Counting Hard-to-Reach Populations: The H2R Training Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
62	DP2AI164315	One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
63	1F31DA060046-01	Dopamine Projections to the Amygdala in Goal-Directed and Habit Learning	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
64	U54DA060049-02	Advancing Tobacco Regulatory Science to Reduce Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
65	1R24DA061190-01	PRIDE-CARES: Patient-Responsive Initiatives for Diverse Engagement – LGBTQ+ Community Action in Research to Eliminate Substance Use Disorder	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(6)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
66	1R01DA061345-01	Race & Place: The Impacts of Racial Inequity on Substance Use and HIV Outcomes in Los Angeles	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
67	1F31DA061593-01	Community and big-data system approaches to identifying and understanding the health impact of xylazine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
68	1K99DA062328-01	The role of valence encoding amygdala ensembles in avoidance behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).

69	8K00DA062570-02	Investigating the role of microglia molecular rhythms in the nucleus accumbens in OUD	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
70	R01AG073440-03	Examining Health Comorbidities and Healthcare Utilization Disparities among Older Transgender and Cisgender Adults in the U.S.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
71	1R01AG089099-01	Social Networks and Cognitive Health among Black and Latino sexual minority men in NJ	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
72	R01HD105655-04S1	Understanding and Supporting Reproductive Decisions Among Women with Developmental Disabilities that Affect Cognition	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
73	5K12GM106996-09	IRACDA at UCLA	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
74	5U01HD108738-03	Harnessing the power of text messaging to reduce HIV incidence in adolescent males across the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
75	R21HD109536	Evaluating Teen-Parent Dynamics in Adolescent COVID-19 Vaccine Acceptance and Uptake	See REASONS FOR EVERY GRANT.
76	1R01HD110428-01A1	Modeling Adolescent Health Care Decision-Making for Vaccines: A Community-Based Participatory Approach	See REASONS FOR EVERY GRANT.
77	1R21HD110617-01A1	Development and Initial Trial of Brief Interventions to Help Parents of Stigmatized Youth Reduce Distress and Strengthen Attachment	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
78	R01MH115765	A couples-based approach to HIV prevention for transgender women and their male partners	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
79	1R01HD115985-01	The California Abundant Birth Project Evaluation: Advancing Birth Equity through Guaranteed Income for Pregnant People	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
80	R25HD116367	Restoring equity to measuring and preventing perinatal intimate partner violence (Remap-IPV)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
81	3P30AI117943-10S1	Third Coast Center for AIDS Research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
82	5R01MH118245-05	Biopsychosocial mechanisms underlying internalizing psychopathology in a prospective, population-based cohort of sexual minority young adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
83	R25MH119858	SHINE Strong: Building the pipeline of HIV behavioral scientists with expertise in trans population health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
84	5R33MH120236-04	Suicide Prevention for Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
85	5R01MH121184-04	Monitoring Microaggressions and Adversities to Generate Interventions for Change (MMAGIC) for Black Women Living with HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
86	5K99NS126639/R00NS126639	Mitochondrial fidelity in mammalian neurons	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
87	5R25MH126703-05	Pipeline to Graduate Education and Careers in Behavioral and Social Science Research for URM Undergraduates: Addressing HIV in Sexual and Gender Minority Communities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
88	5T32MH126772-04	Culturally-focused HIV Advancements through the Next Generation for Equity (CHANGE) Training Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
89	5R21MH128114-02	Strengthening the HIV care continuum for transgender women living with HIV in Malaysia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
90	5R01MH128130-04	STI Response and Recommendations Under PrEP (STIRRUP)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
91	3R01MH128729-03S2	Project STRIVE (STudents Rising above) - Offsetting the health and mental health costs of resilience	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.

92	7R01MH129175-03	Strategies to Prevent HIV Acquisition Among Transgender MSM in the US	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
93	R34MH129187	Brothers building brothers by breaking barriers (B6): A resilience-focused intervention for young Black gay and bisexual men living with HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
94	5R34MH129189-03	Data-driven, peer-led messaging using social media influencers to increase PrEP awareness and uptake among transgender women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
95	R01MH129285	A multi-level approach to improve HIV prevention and care for transgender women of color	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
96	5R01MH130375-02	A longitudinal and experience sampling investigation of rejection sensitivity and its role in sexual minority adolescents' mental health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
97	R34MH132405-01	MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
98	5R01MH132415	Understanding the Regional Ecology of a Future HIV Vaccine	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
99	5R01MH133543-02	Implementing sustainable evidence-based mental healthcare in low-resource community settings nationwide to advance mental health equity for sexual and gender minority individuals	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
100	1R61MH133710-01A1	Targeting Minority Stressors to Improve Eating Disorder Symptoms in Sexual Minority Individuals with Eating Disorders	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
101	4R00DK133804	Utilizing a human stem cell model of the esophagus to understand racial disparities during injury repair	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
102	1K23MH134111-01	Using youth-engaged methods to develop and evaluate a measure for disordered eating behaviors in transgender and gender-diverse youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
103	1F31MH134720-01A1	Understanding Patient Level Implementation Determinants Related to Long-acting Injectable HIV Pre-Exposure Prophylaxis among Young Men Who Have Sex with Men Living in Rural Areas	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
104	5R01MH134721-02	A randomized clinical trial of client-centered care coordination to improve pre-exposure prophylaxis use for Black men who have sex with men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
105	1R21DK134815-01A1	Transforming motivational interviewing into a computable model for automated patient diabetic counseling.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
106	1R34MH134912-01A1	Youth Empowerment and Safety Intervention for Systems-Involved Sexual and Gender Minority Youth at Risk of Suicide	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
107	5K99MH135061-02	Oxytocin receptor signaling modulates social attachment via hippocampal CA2/3 function	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
108	3R01DK135099-02S1	Diversity Supplement for: Impact of a Healthy Checkout Policy on Healthfulness of Grocery Environments and Sales	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
109	R36MH135619	Transcriptomic contributions to the development and evolution of the human cerebral cortex	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
110	5F32MH135634-02	The psychological underpinnings of gender disparities in adolescent mental health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
111	R01MH135738	Know your status: A cluster randomized controlled trial comparing healer-initiated HIV counseling and testing to standard of care in rural South Africa	See REASONS FOR EVERY GRANT.
112	5F99NS135767-02	Neural basis of movement in health and disease	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
113	1K99MH135993-01	Neural circuit dynamics of spatial reward memory	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
114	1R21DK136084-01A1	Mobile pop-up units for diabetes prevention among Hispanics in rural Indiana	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.

115	1F31MH136729-01A1	Determining the role of discrimination in clinical presentation and treatment response among sexual minority people with OCD: A machine learning approach	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o/b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
116	5U01DK137259-02	Renal transplant Equity through Partnership And Structural Transformation (REPAST)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
117	1U01DK137262	CommunityRx - Chronic Kidney Disease (CRx-CKD): An EMR-integrated community resources referral intervention to address structural racism and kidney health disparities in rural North Carolina	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
118	5U01DK137269-02	Mitigating the Effects of Structural Racism on Chronic Kidney Disease Disparities among African Americans	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
119	5U01DK137272-02	NAVIGATE Kidney: A Multi-Level Intervention to Reduce Kidney Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
120	K23MH137389-01	ALIVE: Development and feasibility of a psychosocial intervention for sexual and gender minority autistic adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
121	1R01MH137695-01	Measuring and Mapping Trajectories of Risk and Resilience for Suicidal Thoughts and Behaviors in Sexual and Gender Minority Preteens	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
122	1R34MH137753-01	Developing and pilot testing an eHealth decision support tool for young trans women to improve informed decision making about PrEP	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
123	1R01MH140023-01	Mental Health Effects of Marriage Policy: Evidence from Linked Administrative Data in New Zealand	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
124	5R00GM140269-04	Evolution of Cargo Transport	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
125	1K99DK140511-01	Fcγ Receptor-Mediated Pharmacogenomics of Antibody Therapies in Type 1 Diabetes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
126	5T34GM141986-04	Maximizing Access to Research Careers (MARC) at University of Hawaii at Manoa	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
127	5K99GM146016/4R00GM146016-03	Regulation of zinc-dependent lysosome morphological restructuring, zinc trafficking and low zinc homeostasis in C. elegans and human model systems	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
128	K99GM146243-01	The genetic control of neuronal number and behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
129	5K99GM147825-02	Understanding and rewiring cellular behavior with synthetic biology approaches	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
130	5K99GM148819-02	Elucidating the epigenetic regulation of extracellular matrix and virus-induced fibroblast activation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
131	5R01HL149778-05	Cardiovascular Health of Sexual and Gender Minorities in the Hispanic Community Health Study/Study of Latinos (SGM HCHS/SOL)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
132	K99GM151467-02	Nuclear and chromatin aberrations during non-apoptotic cell death in C. elegans and mammals	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
133	K99GM151473	Characterizing the role of tumor suppressor phase separation and chromatin organization in maintaining genomic integrity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
134	5K99GM152834-02/4R00GM152834-03	Regulation of oxidative stress signaling by tyrosine phosphorylation of antioxidant enzymes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
135	5K99GM152835-02	Testing the functional consequences of rapid centromeric DNA and protein evolution	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
136	1K99GM154059-01A1	RNA and genome regionalization in giant single cells: implications for cellular patterning	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
137	K99GM154061	Investigating UPF3 paralog function in Nonsense-Mediated mRNA Decay and Genetic Compensation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).

138	3R01AI155739-04S1	Diversity Supplement - Environmental surveillance of albendazole resistance markers in human infective helminths using dual amplicon metabarcoding	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
139	1K99GM157463-01	Building Dendrite Architecture via Microtubule Nucleation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
140	K99GM157504	Understanding eukaryotic proteasome assembly regulation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
141	1K99GM159354-01A1	Metabolic regulation of pancreatic metaplasia and neoplasia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
142	5R01HL160326-05	Stigma and the non-communicable disease syndemic in aging HIV positive and HIV negative MSM	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
143	3P01AI165075-01S1	Broad neutralization of pandemic threat coronaviruses	See REASONS FOR EVERY GRANT.
144	R01AI169239	Uptake, safety and effectiveness of COVID-19 Vaccines during Pregnancy	See REASONS FOR EVERY GRANT.
145	5K99HL169908-02	Examining the Role of Structural Factors in Racial and Ethnic Disparities in Cardiovascular Disease	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
146	5K99AI173544-02	Improving phage-based medicine with immunoengineering	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
147	1K99HL173668-01	Resistance Exercise in the Prevention and Treatment of Heart Failure with Preserved Ejection Fraction (HFpEF)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
148	1K99AI182451-01	Molecular understanding of maternal humoral responses to pregnancy	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
149	R01CA237670	Project RESIST: Increasing Resistance to Tobacco Marketing Among Young Adult Sexual Minority Women Using the Inoculation Message Approaches	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
150	1U54CA267730-01	Fostering Institutional Resources for Science Transformation: The FLORIDA-FIRST Health-science Brigade	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
151	5U54CA267776-04	NIH FIRST Cohort Cluster Hiring Initiative at Icahn School of Medicine at Mount Sinai	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
152	1UC2CA293786	ComPASS Health Equity Research Hub at Yale	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
153	U54MD007598	Accelerating Excellence in Translational Science (AXIS)	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
154	5T37MD008636-10	Transdisciplinary Health Disparities Research Training for Native Hawaiians and Pacific Students	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
155	5D43TW012274-03	Integrated Networks of Scholars in Global Health Research Training (INSIGHT)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
156	1R01HG013145-01	Trans/Forming Genomics: Guidance for Research Involving Transgender and Gender Diverse People	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
157	5R01MD013495-05	Health disparities, stress pathways, and stress-related comorbidities among MSM living with HIV	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
158	5R01MD016864-03	K-VAC: Kentucky Vaccinating Appalachian Communities	See REASONS FOR EVERY GRANT.
159	R01MD016880-03	Increasing COVID-19 vaccine uptake among Latinos through a targeted clinical and community-behavioral intervention	See REASONS FOR EVERY GRANT.
160	4R00MD016964-03	Comprehensive computational analysis of genetic and regulatory differences between individuals with African and European ancestries across four brain regions	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.

161	P50MD017349	Chicago Chronic Condition Equity Network	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
162	5R01MD017364-03	REDES: a peer network and mobile health (mHealth) enhanced CHW model to maximize COVID-19 vaccination among low income Latinos	See REASONS FOR EVERY GRANT.
163	1K99MD018451-01A1	Advancing Indigenous Cancer Health Equity through a Community-Centered Framework	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
164	R01MD018459	Elucidating the high and heterogeneous risk of gestational diabetes among Asian Americans: an integrative approach of metabolomics, lifestyles, and social determinants	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
165	R01MD018523	A Multilevel, Multiphase Optimization Strategy for PrEP: Patients and Providers in Primary Care	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
166	5R01MD018679-02	Understanding the Role of Structural Oppression for Suicide Risk among Black Sexual and Gender Minority Adolescents and Young Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
167	5K99MD019060	A Digital Health Intervention to Increase Condom Use Among Adolescent Sexual Minority Males	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
168	1K99MD019292-01	A Multilevel Social Capital Approach to Address Cervical Cancer Screening and Follow Up Delays among Latinas in Safety-Net Settings	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
169	R21MD019345-01A1	Ecological momentary assessment of daily minority stressors and cannabis and tobacco co-use among sexual minority adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
170	1P50MD019475-01	The Institute for Health Equity Research Catalyst Center	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
171	1R21MD019829-01	The Roles of Parental Mental Health and Help-Seeking: Utilizing a Family Systems Approach to Upstream Suicide Prevention for Sexual Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
172	1F31MD019996-01	Advancing Perinatal Health Equity through a Community-engaged Model of Healthcare Services	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
173	1F31MD020261-01	Understanding the Macrosocial Drivers of Cardiovascular Health in the Rural South	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
174	5R01NR020309-04	Harnessing the power of technology to develop a population-based HIV prevention program for trans girls	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
175	5K99DC020570-02/4R00DC020570-03	Identifying neural circuits that support effortful listening	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
176	5R01NR020846-02	#TranscendentHealth - Adapting an LGB+ inclusive teen pregnancy prevention program for transgender boys	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
177	1U24NR021014-02	Advancing Health Equity Through Innovative Community Capacity Building, Data Science & Delivering Community-Centered Structural Interventions & Outcomes: Drexel's ComPASS Coordinating Center (C3)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
178	OT2OD025276	PRIDEnet for the All of Us Research Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
179	5R01AA029044-04	Intersectional Approaches to Population-Level Health Research: Role of HIV Risk and Mental Health in Alcohol Use Disparities among Diverse Sexual Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
180	5R01AA029088-03	A unified protocol to address sexual minority women's minority stress, mental health and hazardous drinking	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
181	4R00AA030601-03	Stigma, Romantic Relationships, and Alcohol Use Among Transgender and Nonbinary Young Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
182	5F31AA030722-02	Examining differential effects of state equality-promoting policies on harmful alcohol use among sexual and gender minority adults in the U.S.: an econometrics approach for causal inference	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
183	1F31AA031420-01A1	Examining Proximal Associations between Minority Stress, PTSD Symptoms, and Alcohol Use among Bi+ College Students with Trauma Histories	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.

184	5R01ES034303-03	Research Employing Environmental Systems and Occupational Health Policy Analyses to Interrupt the Impact of Structural Racism on Agricultural Workers and Their Respiratory Health (RESPIRAR)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
185	OT2OD035659-01	Macro-level Health Considerations of Community and Criminal Justice System Relationships in North Texas	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
186	1K99EB036553-01	AN ADAPTIVE FRAMEWORK TO SYNTHESIZE AND RECONFIGURE BACTERIAL VIRUSES (PHAGES) TO COUNTER ANTIBIOTIC RESISTANCE	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
187	5U01DA036939-10	Multilevel Influences on HIV and Substance Use in a YMSM cohort	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
188	3P2CHD041023-24S1	"Minnesota Population Center" (Note: this is a Diversity Supplement of the Parent Grant)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
189	3P30AI050409-26S1	Center for AIDS Research at Emory University	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
190	R01DA052016	Substance use and DNA methylation at the intersection of sex and gender	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
191	R03DA052651	Improving Sexual Minority Health: Differences in Substance Use, Substance Use Treatment, and Associated Chronic Diseases among Rural versus Urban Populations	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
192	3R01DA055673-03S1	Supplement entitled, "Exploring the accessibility, acceptability, and utilization of a community-based harm reduction vending machine among persons with limited opportunity structures."	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
193	R01DA056235	Structural Influences on Methamphetamine Use among Black Gay and Bisexual Men in Atlanta	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
194	5R01DA056287-02	Comparative- and cost-effectiveness research determining the optimal intervention for advancing transgender women living with HIV to full viral suppression	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
195	5R01DA056888-03	Optimizing PrEP Implementation and Cost-effectiveness among Sexual and Gender Minority Individuals with a Substance Use Disorder	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
196	5R01DA058642-02	Testing a multistage model of risk factors for cannabis use utilizing a measurement burst design among sexual minority women, sexual minority gender diverse individuals, and heterosexual women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
197	5R01MD012793-05	Advancing novel methods to measure and analyze multiple types of discrimination for population health research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
198	3R01MD015165-04S1	Multilevel Physical Activity Intervention for Low Income Public Housing Residents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o(b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
199	5T32MH020004	Research Training in Late-Life NeuroPsychiatric Disorders	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
200	1R01NR020583-01	Ending the HIV Epidemic with Equity: An All-facility Intervention to Reduce Structural Racism and Discrimination and its Impact on Patient and Healthcare Staff Wellbeing	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
201	R01NR021098	Evaluating the Implementation and De-Implementation of Pandemic Era SNAP Expansion Policies on Diet and Health: A Mixed Methods Project	See REASONS FOR EVERY GRANT.
202	1F31NR021239-01	Personal Healthcare Networks of Transgender and Gender-Diverse Adults After Gender-Affirming Surgery	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
203	R00AA028049	A mixed-methods approach to understanding stress and hazardous drinking among same-sex female couples	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
204	T32DA031099-13	Substance Abuse Epidemiology Training Program (SAETP) at Columbia University	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
205	1K01DE033040-01A1	Developmental mechanisms in the formation and function of sensory-motor circuits responsible for suckling and mastication.	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
206	U01OD033248	TransHealthGUIDE: Transforming Health for Gender-Diverse Youth Using Interventions to Drive Equity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

207	3OT2OD035592	Proyecto Juntos	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
208	5UM1AI068619-19	Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation for Transgender Women in the Americas: A Vanguard Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
209	3R01AG075734	Training the Long-Term Services and Supports Dementia Care Workforce in Provision of Care to Sexual and Gender Minority Residents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
210	5UM2HD111076-03	Operations and Collaborations Center - Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Operations and Collaborations Center (UM2 Clinical Trial Optional)	See REASONS FOR EVERY GRANT.
211	1K23HD112599-01A1	Caregiver decision making for seasonal respiratory vaccines for children	See REASONS FOR EVERY GRANT.
212	1R21HD116080-01	Confidentiality in use of health insurance coverage for reproductive health services	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
213	R01MH130007	Understanding the Interplay between Parent and Child Contributions in Parent-Child Anxiety Transmission	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
214	5K99MH133994-02	Computational and neurodevelopmental mechanisms of memory-guided decision-making	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
215	1R38MH135609-01	An intersectional approach to transgender and/or nonbinary college student mental health: The role of gender identity, race/ethnicity, socioeconomic status, and campus policy	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
216	5K99NS135649-02	Computational Methods for Precise Holographic Control and Mapping of Neural Circuits	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
217	5K99GM144750-02	Dynamic mechanisms of transcriptional coactivator function in Notch signaling	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
218	5K99GM148723-02	Stress tolerant annual killifish: a new model for the cellular stress response	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
219	1R15GM152943-01	"Mathematical Modeling and Scientific Computing for Infectious Disease Research."	See REASONS FOR EVERY GRANT.
220	5K99GM153720-02	Dissecting the synaptic and circuit mechanisms underlying olfactory-driven social behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
221	1K99GM154060-01	TULP3 integrates essential ciliary functions	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
222	1K99GM157508-01	Unraveling the role of molecular capacitors that obscure cryptic genetic variation in Astyanax mexicanus during the evolution of eye loss	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
223	5K99HL166700-02	Investigating relationships between naturalistic light exposure and sleep	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
224	5P01AI168148-02	Leptospiral-Phagocyte Dynamics in Leptospirosis	See REASONS FOR EVERY GRANT.
225	1U19AI171401-01	Metropolitan AntiViral Drug Accelerator	See REASONS FOR EVERY GRANT.
226	R01CA251478	Local Flavor Policies to enhance equity in tobacco	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
227	R34CA283483-02	Multi-level school-based intervention to improve HPV vaccine uptake and completion in South Africa	See REASONS FOR EVERY GRANT.
228	5K99MD018629-02	Racism-related stress and birth outcomes among Latinas: New tools for maximizing conceptual and methodological validity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
229	5K01AG056669-05	The Epidemiology of Alzheimer's Disease and Related Dementias in Sexual and Gender Minority Older Adults: Identifying Risk and Protective Factors	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

230	5R24AG066599-03	Building Community and Research Engagement among Sexual and Gender Minority Older Adults at Risk for Alzheimer's Disease and Related Dementias	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
231	5R01AG083177-02	Enhancing Measurement and Characterization of Roles and Experiences of Sexual and Gender Minority Caregivers of Persons living with Alzheimer's Disease and Related Dementias	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
232	2T32GM135742-06	UCSC IMSD	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
233	5R01MD016250-03	Assessing Cervical Cancer Healthcare Inequities in Diverse Populations: The ACHIEVE Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
234	5R01CA274564-03	Impact of Allostatic Load and Neighborhood Contextual Factors on Breast Cancer in the Women's Health Initiative	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
235	T32GM141882	Genetic Approaches to Development and Disease	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
236	U01AI156875-04	Digital, Limited Interaction Efficacy Trial of LifeSkills Mobile to Reduce HIV Incidence in Young Transgender Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
237	5R01MH134051-02	A Strengths-Based, Intersectional Approach to Suicide Prevention Among Black Sexual and Gender Minority Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
238	1R01HL169503-01A1	Geographically-Explicit Ecological Momentary Assessment Protocol to Assess the Linkages Between Intersectional Discrimination and CVD Risk Among Sexual and Gender Minorities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
239	1OT2OD037655-01	Building a Diverse Network to Support and Build Pathways for Historically Underrepresented Students in Quantitative-Focused Research Areas Within the All of Us Research Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
240	1K99NS133031-01A1	A comparative approach to uncovering the cellular and circuit basis of the role of the corticospinal tract in motor skill	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
241	1K99EY034700-01	Processing of visual information by spatial memory circuits in the avian brain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
242	5R01MH131475-02	Intervention to Enhance PrEP Persistence Among African-American Men Who Have Sex with Men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
243	5R21MD019388	Integrated Network Analysis of RADx-UP Data to Increase COVID-19 Testing and Vaccination Among Persons Involved with Criminal Legal Systems (PCLS)	See REASONS FOR EVERY GRANT.
244	1RF1MH132348-01	Improving Mental Health Among the LGBTQ+ Community Impacted by the COVID-19 Pandemic	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
245	5T32MH013043-53	Research Training Program in Psychiatric Epidemiology	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
246	5T32AI148099-04	Training in Translational Immunology Research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
247	1K01DA057880-01A1	Stigma, drug use, and HIV vulnerability among Hispanic and Latino sexual minority men	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
248	K24DA057874	Mentoring the next generation of substance use, HIV, and epigenetic researchers in sexual and gender minority health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
249	5K00NS115338-05	Circuit reconstruction of functionally-identified neurons in deep brain regions: application to grid cells	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
250	R01MH138297-01	The SUSTAIN 2 study - SUStained HIV treatment for adherence after interruption in care	See REASONS FOR EVERY GRANT.
251	5R01MH130277-05	Transgender-Specific Differentiated HIV Care: An Implementation Science Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
252	5R01MD016755-05	Creating Access to Resources and Economic Support (CARES)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.

253	5R01MH133260-02	Integration of a collaborative care model for mental health services into HIV care for pregnant and postpartum women in Kenya (the Tunawiri Study)	See REASONS FOR EVERY GRANT.
254	4R00AI166094-03	Stress-induced transposon mobilization in the human fungal pathogen Cryptococcus	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
255	5R01NR021019-03	Enhancing Structural Competency in School-Based Health Centers to Address LGBTQ+ Adolescent Health Equity	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
256	T32DC000038	Training for Speech and Hearing Sciences	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
257	OT2OD035845-01	Humanitarian Health Care Network: Bringing the Most Vulnerable to Care	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
258	1R21AI183907-01A1	Applying a Behavioral Economic Approach on PrEP and Hormone Options among Transgender Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
259	5P30CA015704-49	Cancer Center Support Grant	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
260	R25LM014575	Advancing Gender and Health Justice Research and Education	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
261	OT2OD035877-01	Achieving Optimal Sexual and Reproductive Health (SRWH Project)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
262	4R00HL157611-03	Toward Accurate Cardiovascular Disease Prediction in Hispanic/Latinos: Modeling Risk and Resilience Factors	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
263	1OT2OD035935-01	Leveraging a community-driven approach to address the impact of social determinants of health on structural inequities among Miami-Dade County's intergenerational LGBTQ+ Community	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
264	5K00MH132569-06	Developing multimodal biomarkers of cognitive ability in a genetic model of neurodevelopment	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
265	5K01MD019325-02	Enlace Familiar: Combating Mental Health Stigma, Improving Mental Health Literacy, Supporting Mental Health Discussions at Home, and Access to care among Latinx Adolescents from Mixed Status Families	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
266	5F31EY035165-02	Linking endoplasmic reticulum calcium handling to neuronal function in vivo in the Drosophila visual system	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
267	5R01MH123282-05	NEXUS: A novel social network approach to study the effects of intersectional stigma on HIV prevention among Latino MSM	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
268	1K99MH135212-01A1	Mapping Neural Dynamics in Hormone-sensitive Networks	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
269	T32GM135751	IMSD at the University of Massachusetts Chan Medical School	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
270	1K99HG013676-01	Using the continuum of genetic causality to investigate trans regulatory mechanisms	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
271	K99EY036650	Delineating the neural computational network for object recognition	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
272	5K99DA059613	Decoding Neuropeptide S Modulation of OFC-mediated Reward Seeking	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
273	D43TW011324	Malaysian Implementation Science Training (MIST) Program in HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
274	5R01TW012674-02	Reducing Stigma in People Who Inject Drugs with HIV Using a Rapid Start Antiretroviral Therapy Intervention	See REASONS FOR EVERY GRANT.
275	K99MD018671	Delineating the Role of the Homocysteine-Folate-Thymidylate Synthase Axis and Uracil Accumulation in African American Prostate Tumors	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.

276	T32GM148391-02	IMSD at Emory University	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
277	5T34GM149511-02	MARC at Emory University	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
278	1R25AI175048-01A1	INfectious Diseases Summer Program Integrating Research at Emory (INSPIRE)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
279	5K12GM000680	IRACDA Fellowships in Research and Science Training (FIRST)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
280	1R01MH135498-01A1	Using digital photovoice to explore the relationships between social media content and suicidality among transgender adolescents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
281	1R34MH129782	CA-LINC: A Culturally Adapted Care Coordination Suicide Detection and Intervention Model for Black Youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
282	K99/R00DC021581	Neural circuitry and population dynamics for perception of social vocalizations in the auditory pathway	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
283	R01TW012392	Buddhism and HIV Stigma in Thailand: An Intervention Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
284	R01TW012392-03S1	Buddhism and HIV Stigma in Thailand: An Intervention Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
285	3R37MH119194-05S1	Neurodevelopmental Mechanisms Underlying Stress Vulnerability during Adolescence	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
286	1R01HD112464-01A1	Health and economic consequences of changing federal and state policies on reproductive health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
287	5R25GM142065-04	Project SCORE (Student-Centered Outcomes Research Experience)	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
288	1R01DK135838-01	The Role of Structural Racism on Disparities in Clinical Outcomes for Diabetes: A Mixed Methods Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
289	1R36MH134774-01A1	The Effects of Structural Inequities and Syndemics on Willingness to Participate in HIV Research among Black Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
290	5T34GM145511	U-RISE @ UC Merced	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
291	5U54HG013243-02	Administrative Core: Pacific Center for Genomic Research - Centers in Genomic Research	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
292	3U24MD016258-03S2/5U24MD016258-03	RADx-UP CDCC	See REASONS FOR EVERY GRANT.
293	3T34GM141986-03S1	One Health Research Training for Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
294	F31AG087648-01	Network drivers of regional vulnerability to early Alzheimer's disease pathology	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
295	1F31HD113328-01A1	Mapping the cellular impacts of Chd8 haploinsufficiency and characterizing microglial activity in Chd8 mutant mice	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
296	1K99AG088361-01	Patterns and Mechanisms Underlying Somatic Mutations Across Long-Lived Bats	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
297	5K99EY035758-02	Understanding how mitochondrial interaction with other organelles in the retinal pigment epithelium (RPE) affect its function in the outer retina	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
298	3R01GM141329-04S1	Investigating the metal-dependent function, allostery and inhibition of CRISPR-Cas9	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).

299	5F31MD018931-02	Hardship and Survival: The Impact of Migration-Related Trauma, Communal Coping, and Social Stressors on the Suicide and Mental Health Outcomes of Latina Immigrant Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
300	1F31DA059262-01A1	Exploration of the unique neurobehavioral profile of sequential opioid-stimulant polysubstance use disorders	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
301	F31NR021235-01	Examining Health Disparities in the use of Hematopoietic Cell Transplants for HIV- related Lymphoma	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
302	5T32DK007647	Graduate Training in Nutrition	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
303	1R36DA061635-01	Dissecting the role of loneliness on substance use- and HIV-related outcomes among sexual minority men in the United States and Canada	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
304	T32HD049339-16	GSH Training Grant	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
305	T34GM136450	U-RISE Training the Next Generation of Basic Biomedical Researchers a Holistic Approach	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
306	T32MH128395	Social Determinants of HIV	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
307	5F31HL168956-02	Mechanisms Underpinning Afterload-Induced Atrial Fibrillation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
308	R21MH135489-02	Leveraging Latinx Adolescents, Photovoice, and Longitudinal Data to Disentangle the Bidirectional Effects of Social Media and Mental Health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
309	T32GM145440	Medical Scientist Training Program	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
310	F99NS134207	Neurocomputational Mechanisms of Affective Semantic Memory Development	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
311	1F31HL178310-01	Investigating cellular adaptation to one-carbon metabolism perturbation	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
312	3R01GM072551-19S1	Synaptonemal complex assembly and function in meiosis	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
313	1F31DC022153-01	Leveraging human intracranial recordings to quantitatively characterize basal ganglia output during speech	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
314	1F31EY036742-01	Transcriptional and Developmental Basis of the Human X-linked Homeotic Hotspot	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
315	5T32MH096679-12	Research Training in Biobehavioral Disturbances of Eating Disorders	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
316	R01MD016417	Contextual Determinants of Sexual Minority Health in the United States	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
317	1R01CA276594-01	Randomized Controlled Trial of Dyadic Financial Incentive Treatment for Dual Smoker Couples: Evaluation of Efficacy, Mechanisms, and Cost Effectiveness	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
318	1F31CA281083-01A1	Understanding and Exploiting Apoptotic Dysregulation in Ovarian Cancer	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
319	K23MH137389-01	ALIVE: Development and feasibility of a psychosocial intervention for sexual and gender minority autistic adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
320	5R25GM142044-03	Frugal Science Academy: Training K-12 innovators and democratizing synthetic biology tools	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
321	K99ES035895	Spatiotemporal effects and associations between deforestation and alcohol and tobacco use in Indonesia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).

322	L60AA031839	A mixed-methods approach to understanding depression, suicide risks, and alcohol and other drug use among same-sex female couples	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
323	UH3AI169655-03	Multilevel strategies to understand and modify the role of structural and environmental context on HIV inequities for sexual and gender minorities of color	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
324	R01DA056264-03	Measuring the impact of structural racism and discrimination during adolescence on substance use, psychological distress	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
325	R01NR019512-03	Harnessing the power of peer navigation and mHealth to reduce health disparities in Appalachia	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
326	R37AG076057	How spouses influence each other's health in same- and different-sex marriages: A longitudinal and dyadic assessment from mid to later life	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
327	T32GM141862	G-RISE at UC Merced	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
328	5K99ES034819-02	Impact of Biomass Burning Aerosol and Humic-like Substances on Iron Homeostasis and Atherosclerosis	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
329	T32MH018870	Training in Schizophrenia and Psychotic Disorders: From Animal Models to Patients	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
330	1F31MD019985-01	Characterizing Economic Determinants of Violence and Safety Disparities Among Sexual and Gender Diverse Populations	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
331	5K99EY034700	Processing of visual information by spatial memory circuits in the avian brain	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
332	5R00CA260718-04	Testing the effect of anti-tobacco message framing on polytobacco use in lesbian, gay, bisexual, and transgender young adult adults	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
333	1R01CA284032	Evaluating Centralizing Interventions to Address Low Adherence to Lung Cancer Screening Follow-up in Decentralized Settings	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
334	5R25GM142087-04	Engineering Solutions for Better Health: Genetic Technology and Biomedical Engineering for Secondary Classrooms	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
335	1R25GM154387-01	The Biology of Climate Change: Impacts on Human Health and the Science of Solutions	See REASONS FOR EVERY GRANT.
336	T34GM149493	U-Rise at Cal State Fullerton	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
337	5K99NS129759-02	Investigating Descending Control of Walking	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
338	R21MH133755-01	The TAIL-PrEP Study: Acceptability and Feasibility of a Tailored Adherence Intervention for safe discontinuation of Long-acting PrEP	*See* REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
339	5U54CA132381-18	Partnership for the Advancement of Cancer Research: NMSU & Fred Hutch	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(ii), 283p, 285t, and/or 289a-2.
340	5T32GM138075-04	Bridges to the Doctorate Research Training Program at California State University Long Beach	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
341	T32ES007142	Graduate Training in Biostatistics	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
342	4R00DA055508-03	A Gender-Affirming Stigma Intervention to Improve Substance Misuse and HIV Risk among Transgender Women	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
343	F99NS129176-02	Mechanistic description of tolerance/withdrawal from opioids in the paraventricular nucleus of the thalamus	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
344	1K99DC021727-01	Neuroplasticity and early cochlear implant use	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).

345	1F99NS139546-01	Neuro-Evolutionary Basis of Vertebrate Social Behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
346	5F31CA275157	The Role of the Fructose-1,6-Bisphoshatase 2 and c-Myc Interaction in Sarcoma Progression	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
347	R00DA056842	Native Spirit: Culturally-grounded substance use prevention for Indigenous adolescents	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(ii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
348	5R01MD018051-03	Modeling Resilience as a Multidimensional Protective Factor for Transgender Health Disparities: Measure Development and Longitudinal Evaluation of Resilience	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
349	5F31AA030907-02	Hitting Close to Home: A Multi-Method Investigation of Neighborhood Characteristics and Drinking Motives on Alcohol-Related Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
350	U01NR021576	Meet Me on the Pitch: Developing and testing a community-based sports and behavioral health intervention for newcomer youth	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
351	K99/R00K99MH127471	Distributed neural activity patterns underlying practice-based learning	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
352	5K99HD108801-02	Sex, Physiological State, and Genetic Background Dependent Molecular Characterization of CircuitsGoverning Parental Behavior	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
353	5R01AI179873-02	The basis of Influenza A virus strain-dependent reassortment potential	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
354	5T34GM149492-02	U-RISE at Cal Poly	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
355	3R01DK133453-02S1	Leveraging early-life microbes to prevent type 1 diabetes	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
356	5R01CA276500-02	Smoking and Cancer-Related Health Disparities among Sexual and Gender Minority Adults	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
357	3R01HL161049-03S1	Addressing System-level Barriers to COPD Guideline Concordant Care	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
358	1F31GM154412-01	The Role of Post-Translational Modifications in Bacterial Responses to Methylglyoxal	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
359	5R01HG011405-04	Elucidating the phenome-wide impact of sex and gender on disease	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
360	R01MD019763-01	A community driven modeling approach for identifying community & policy-level interventions to address the impact of structural racism and discrimination on adolescent substance use and mental health	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
361	5R01AA029989-04	Long-term and Daily Associations among Intersectional Minority Stress, Structural Oppression, and Alcohol Use and Misuse among Sexual Minority Adolescents of Color	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
362	5T32ES007322-23	Advanced training in environmental health and data science: molecules to populations	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o(b)(2), 285t-1(a)(b), and/or 288(a)(4).
363	1R01DC021839-01	Family language planning and language acquisition among deaf and hard of hearing children	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(h), 282(m)(2)(B)(iii), 283o (b)(2), 283p, 285t, 285t-1(a)(b), 288(a)(4), and/or 289a-2.
364	1P50MH129708-01A1	UW Practice-based Suicide Prevention Research Center	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(h), 283o (b)(2), 285t-1(a)(b), and/or 288(a)(4).
365	3R01DK135838-02	The Role of Structural Racism on Disparities in Clinical Outcomes for Diabetes: A Mixed Methods Study	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
366	R25MH067127	Training for Scientists Conducting Research to Reduce HIV/AIDS Health Disparities	See REASONS FOR EVERY GRANT. In addition, the Directives and terminations are also in excess of statutory authority and contrary to statute—and also violate the separation-of-powers principle of the U.S. Constitution—because of, among other statutes: 42 U.S.C. §§ 282(b)(8)(D)(ii), 282(m)(2)(B)(iii), 283p, 285t, and/or 289a-2.
367	5R01MH133266-02	Integration of stepped care for Perinatal Mood and Anxiety Disorders among Women Living with HIV in Kenya	See REASONS FOR EVERY GRANT.

Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

APPENDIX - VOLUME IV

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TABLE OF CONTENTS

ADDENDUM

Memorandum and Order on
Subject Matter Jurisdiction (25-cv-10814 Dkt. No. 105)..... A1

Memorandum and Order on
Motion to Dismiss (25-cv-10787 Dkt No. 84)..... A29

Transcript of Consolidated June 16, 2025, Bench Trial
(25-cv-10787 Dkt. No. 143) (25-cv-10814 Dkt. No. 156)..... A73

Partial Final Judgment 25-cv-10814
(25-cv-10814 Dkt. No.151)..... A161

Partial Final Judgment 25-cv-10787
(25-cv-10787 Dkt. No. 138)..... A163

Findings of Fact, Rulings of Law, and
Order for Partial Separate and Final Judgment
(25-cv-10787 Dkt. No. 151) (25-cv-10814 Dkt. No. 163)..... A166

Order Denying Motion to Stay Pending Appeal
(25-cv-10787 Dkt. No. 147) (25-cv-10814 Dkt. No. 160)..... A269

VOLUME I

Docket Report for *American Public Health Association, et al. v. National Institutes of Health, et al.*, Case No. 25-cv-10787 (APHA Case)..... A275

Docket Report for *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, Case No. 25-cv-10814 (States Case)..... A328

Complaint in APHA Case
(APHA Case Dkt. No. 1)..... A380

Amended Complaint in States Case
(States Case Dkt. No. 75)..... A458

Notice of Appeal APHA Case
(APHA Case Dkt. No. 139) A550

Notice of Appeal States Case
(States Case Dkt. No. 152) A553

NIH Review of Agency Priorities Based on the New Administration's Goals
February 12, 2025 (NIH_GRANTS_9) A556

Supplemental Guidance to Memo
February 13, 2025 (NIH_GRANTS_16) A557

Directive on NIH Priorities
February 21, 2025 (NIH_GRANTS_2930-31) A558

Award Assessments for Alignment with Agency Priorities
March 4, 2025 (NIH_GRANTS_2135-72) A560

Award Revision Guidance
March 13, 2025 (NIH_GRANTS_1957-58) A598

Award Assessments for Alignment with Agency Priorities
March 25, 2025 (NIH_GRANTS_3216-30) A600

Alignment with Priorities
May 7, 2025 (NIH_GRANTS_3547-81) A615

Alignment with Priorities
May 15, 2025 (NIH_GRANTS_3516-46) A650

Transcript of Consolidated May 8, 2025, Hearing
(25-cv-10814 Dkt. No. 107) A681

Transcript of Consolidated May 13, 2025, Hearing
(25-cv-10814 Dkt. No. 110) A709

Transcript of Consolidated June 3, 2025, Status Conference
(25-cv-10814 Dkt. No. 107) A740

VOLUME II - DECLARATIONS

Declaration Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-19	Declaration of Plaintiff Brittany Charlton	All.	A768
38-20	Declaration of Plaintiff Katie Edwards	1–13	A864
38-21	Declaration of Plaintiff Nicole Maphis	1–7	A876
38-22	Declaration of Plaintiff Peter Lurie	1–6	A883
38-23	Declaration of Georges C. Benjamin On behalf of Plaintiff American Public Health Association (APHA)	All.	A888
38-24	Declaration of Plaintiff Ibis Reproductive Health	1–10	A976
38-25	Declaration of Neal Sweeney On behalf of Plaintiff United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)	All.	A985
38-26	Declaration of Jeremy Berg	All.	A991
38-27	Declaration of Scott Delaney	All.	A1009
38-28	Declaration of APHA Member 1	1–10	A1091
38-29	Declaration of APHA Member 2	1–10	A1100
38-30	Declaration of APHA Member 4	1–9	A1109
38-31	Declaration of APHA Member 5	1–9	A1117
38-32	Declaration of APHA Member 7	1–24	A1125
38-33	Declaration of APHA Member 9	All.	A1148
38-34	Declaration of APHA Member 10	1–9	A1204

38-35	Declaration of UAW Pre-Member 1	1–7	A1212
38-36	Declaration of UAW Pre-Member 7	1–7	A1218
38-37	Declaration of UAW Member 3	1–8	A1224
38-38	Declaration of UAW Member 9	1–5	A1231
38-39	Declaration of UAW Member 10	1–8	A1235
38-40	Declaration of UAW Member 11	All.	A1242
38-41	Declaration of UAW Member 12	1–7	A1286
38-42	Declaration of UAW Member 13	1–5	A1292
72-3	Supplemental Declaration of Scott Delaney	All.	A1296
72-4	Supplemental Declaration of Jeremy Berg	All.	A1305
72-10	Supplemental Declaration of Plaintiff Nicole Maphis	1–3	A1316
72-12	Supplemental Declaration of Plaintiff Katie Edwards	All.	A1318
103-3	Second Supplemental Declaration Of Scott Delaney	All.	A1322
103-4	Second Supplemental Declaration Of Katie Edwards	All.	A1352

VOLUME III - EXHIBITS

Exhibits Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-01	NIH Webpage titled "Institutes at NIH"	All.	A1356

38-02	NIH webpage titled "Budget" (last updated on October 3, 2024)	All.	A1357
38-03	NIH webpage for Notice Number: NOT-OD-25-084, "NIH Operates Under a Continuing Resolution" (published April 3, 2025)	All.	A1360
38-04	Excerpt of NIH-wide Strategic Plan, Fiscal Years 2021-2025	All.	A1361
38-05	Excerpt of April 2024 NIH Grant Policy Statement	All.	A1405
38-06	March 14, 2025, Article from *The Atlantic* by Katherine J. Wu, titled "The NIH's Grant Terminations are 'Utter and Complete Chaos.'"	All.	A1424
38-08	Transcript of April 3, 2025, Deposition of Michelle Bulls in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 48-50, 68-76, 92-93, 99-102	A1439
38-09	Transcript of April 3, 2025, Deposition of Liza Bundesen in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 38-39	A1458
38-16	NIH Minority Health and Health Disparities Strategic Plan 2021-2025	All.	A1461
72-01	NIH webpage titled "Contracts"	All.	A1499
72-05	March 2025 Kirschstein NRSA Funding Opportunity	All.	A1506
72-06	January 2025 Kirschstein NRSA Funding Opportunity	All.	A1526
72-07	NIH webpage titled "Updates to NIH Institutional Training Grant Applications" (last updated March 25, 2025)	All.	A1542

72-08	March 11, 2025, Memo from Matthew Memoli with subject line "Initial Actions Regarding President Trump's Executive Orders – INFORMATION"	All.	A1550
72-09	April 8, 2021, Document Titled "Research General Terms and Conditions Agency Specific Requirements for the National Institutes of Health (NIH)"	All.	A1597
138-1	May 27, 2025, Spreadsheet of Grants	All.	A1603
138-2	June 13, 2025, Spreadsheet of Grants	All.	A1619

VOLUME IV - EXCERPTS FROM THE ADMINISTRATIVE RECORD

Excerpts from the Administrative Record
(from NIH_GRANTS_00001 to NIH_GRANTS_03578) A1636

VOLUME V - ADDITIONAL EXCERPTS FROM THE ADMINISTRATIVE RECORD

Additional Excerpts from the Administrative Record
(from NIH_GRANTS_03585 to NIH_GRANTS_05676) A2334

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

TO: Heads of Operating Divisions Head
Heads of Staff Divisions

THROUGH: Wilma M. Robinson, Ph.D., Deputy Executive Secretary

FROM: Dorothy A. Fink, MD, Acting Secretary

DATE: January 21, 2025

SUBJECT: Immediate Pause on Issuing Documents and Public Communications – ACTION

As the new Administration considers its plan for managing the federal policy and public communications processes, it is important that the President's appointees and designees have the opportunity to review and approve any regulations, guidance documents, and other public documents and communications (including social media). Therefore, at the direction of the new Administration and consistent with precedent, I am directing that you immediately take the following steps through February 1, 2025:

1. Refrain from sending any document intended for publication to the Office of the Federal Register until it has been reviewed and approved by a Presidential appointee. Please note that the Office of the Executive Secretary (Exec Sec) withdrew from OFR all documents that had not been published in the Federal Register to allow for such review and approval.
2. Refrain from publicly issuing any document (e.g., regulation, guidance, notice, grant announcement) or communication (e.g., social media, websites, press releases, and communication using listservs) until it has been reviewed and approved by a Presidential appointee.
3. Refrain from participating in any public speaking engagement until the event and material have been reviewed and approved by a Presidential appointee.
4. Coordinate with Presidential appointees prior to issuing official correspondence to public officials (e.g., members of Congress, governors) or containing interpretations or statements of Department regulations or policy. Nothing in this guidance is intended to limit an employee's personal correspondence with members of Congress or other third parties, including an employee's whistleblower protected communications.
5. Notify Exec Sec promptly of any documents or communications that you believe should not be subject to the directives in paragraphs 1-4 because they are required by statute or litigation; affect critical health, safety, environmental, financial, or national security functions of the Department; or for some other reason. Please provide the title, a brief summary, the target release date, and the rationale for expedited release to your Exec Sec Policy Coordinator.

The President's appointees intend to review documents and communications expeditiously and return to a more regular process as soon as possible.

If you identify any actions taken inconsistent with these requests, please know they shall not be considered impliedly ratified. These items should be immediately withdrawn or rescinded to deem them as void and without effect.

Thank you for your assistance in ensuring a smooth transition consistent with our nation's democratic principles.

Dorothy A. Fink, MD, Acting Secretary

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

TO: OPDIV Heads and StaffDiv Heads

FROM: Acting Secretary

DATE: January 20, 2021

SUBJECT: Immediate Action on Regulatory Review – **ACTION**

As the new Administration considers its plan for managing the Federal regulatory process, it is important that President Biden's appointees and designees have the opportunity to review and approve any new or pending regulations or guidance documents. Therefore, at the direction of the new Administration and consistent with past precedent, I am directing that you immediately take the following steps:

1. Refrain from sending proposed or final regulation or other notice or other document (e.g., guidance) intended for publication to the Office of the Federal Register (the "OFR") for publication unless and until it has been reviewed and approved by me or my designee after the issuance of this memorandum.
2. Work with the Office of the Executive Secretary (ES) to withdraw from the OFR all proposed or final regulations that have not been published in the Federal Register so that they can be reviewed and approved as described in paragraph 1. This withdrawal must be conducted consistent with OFR procedures.
3. Refrain from issuing subregulatory or significant guidance between now and February 3, during which time you will have the opportunity to brief President Biden's appointees and designees on any such guidance that was intended to be issued.
4. Coordinate with President Biden's appointees prior to issuing official correspondence to public officials (e.g., Members of Congress, Governors) or containing interpretations or statements of Department regulations or policy to ensure President Biden's appointees and designees have an opportunity to consider any such official correspondence before it is issued by the Department. Nothing in this guidance is intended to limit an employee's personal correspondence with members of Congress or other third parties, including an employee's whistleblower protected communications.
5. Provide, by close of business on January 23, to the Office of the Executive Secretary, a list of all documents withdrawn pursuant to paragraphs 2.
6. Notify me or the Deputy Executive Secretary promptly of any regulations that you believe should not be subject to the directives in paragraphs 1-4 because they are required by statute or litigation, affect critical health, safety, environmental, financial, or national security functions of the Department, or for some other reason. The only exemptions to paragraphs 1-4 will be for any COVID-19 related documents. These urgent documents will be handled directly with ES via the COVID-19 clearance process.

If you identify any actions taken inconsistent with these requests, please know they shall not be considered impliedly ratified and please immediately withdraw or rescind them as void and without effect.

Thank you for your assistance in ensuring a smooth transition consistent with our nation's democratic principles.

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, M.D., Acting Secretary

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

February 10, 2025

NOTE TO: THE CHIEF OF STAFF
HEATHER FLICK

SUBJECT: **UPDATE** – Temporary Restraining Order – *New York, et al.* v. *U.S. Office of Management and Budget* (No. 25-cv-39) (Feb. 10, 2025, D. R.I.)

This afternoon, the district court in the above-captioned case issued a further order directing the Defendants, including the Department of Health and Human Services, to resume payments previously paused as a result of an executive order and directives from the Office of Management and Budget (OMB). In its order, the court addressed the argument that some continued pauses in funding were made pursuant to possible findings of fraud. The court rejected that argument and held that such funding pauses, *viz.*, payment pauses made to "root out fraud," violate the plain text of the court's original temporary restraining order. Based on the Rhode Island District Court's order of this afternoon, and after consulting with the Department of Justice, this office provides the following guidance: ***All payments that are due under existing grants and contracts should be un-paused immediately.***

The two Secretarial Directives, one regarding ACF payments to ORR grantees and vendors and the other dealing with DEIA-related payments, that were issued last week and this morning, respectively, do not change this advice; any payments paused pursuant to those Directives should also be un-paused.

Please note, the new order requires HHS to restore all frozen funding, even if it has been paused as the result of agency discretion. If you have questions as to whether payments may be paused or remain paused because the agency's actions were made independent of the President's Executive Orders or OMB direction, please consult with your usual contact in the Office of the General Counsel (OGC). However, until and unless you receive advice from OGC or direction from the Secretary otherwise, such payments should be un-paused.

Sean R. Keveney
Acting General Counsel

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

SECRETARIAL DIRECTIVE ON DEI-RELATED FUNDING

February 10, 2025

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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

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
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)

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

February 12, 2025

NOTE TO: THE CHIEF OF STAFF

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

This morning, the District Court in the above-captioned case issued a further order clarifying that the Temporary Restraining Order and associated orders allow the defendant agencies, including the Department of Health and Human Services (HHS), to limit access to federal funds on the basis of applicable authorizing statutes, regulations, and terms. The Court further confirmed that its Orders do not bar defendant agencies from exercising their own lawful authorities to withhold funding without the prior approval of the Court.

Accordingly, agency components may resume implementation of the following two Secretarial directives: (1) Secretarial Directive on Program and Payment Integrity, issued February 3, 3025, regarding the Office of Refugee Resettlement's administration of the Unaccompanied Alien Children Program; and (2) Secretarial Directive on DEI-Related Funding, issued February 10, 2025.

Sean R. Keveney
Acting General Counsel

Sean R. Keveney -S
Digitally signed by Sean R. Keveney -S
Date: 2025.02.12 15:45:26 -05'00'

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF RHODE ISLAND; STATE OF NEW JERSEY; COMMONWEALTH OF MASSACHUSETTS; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF MAINE; STATE OF MARYLAND; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NORTH CAROLINA; STATE OF NEW MEXICO; STATE OF OREGON; STATE OF VERMONT; STATE OF WASHINGTON; and STATE OF WISCONSIN,

Plaintiffs,

v.

DONALD TRUMP, *in his Official Capacity as President of the United States*; U.S. OFFICE OF MANAGEMENT AND BUDGET; MATTHEW J. VAETH, *in his Official Capacity as Acting Director of the U.S. Office of Management and Budget*; U.S. DEPARTMENT OF THE TREASURY; SCOTT BESSENT, *in his Official Capacity as Secretary of the Treasury*; PATRICIA COLLINS, *in her Official Capacity as Treasurer of the U.S.*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOROTHY A. FINK, M.D., *in her Official Capacity As Acting Secretary Of Health And Human Services*; U.S. DEPARTMENT OF EDUCATION; DENISE CARTER, *in her Official Capacity as Acting Secretary of Education*; U.S. FEDERAL EMERGENCY MANAGEMENT AGENCY; CAMERON HAMILTON, *in*

C.A. No. 25-cv-39-JJM-PAS

his Official Capacity as Acting Administrator of the U.S. Federal Emergency Management Agency; U.S. DEPARTMENT OF TRANSPORTATION; JUDITH KALETA, *in her Official Capacity as Acting Secretary of Transportation*; U.S. DEPARTMENT OF LABOR; VINCE MICONE, *in his Official Capacity as Acting Secretary of Labor*; U.S. DEPARTMENT OF ENERGY; INGRID KOLB, *in her Official Capacity as Acting Secretary of the U.S. Department of Energy*; U.S. ENVIRONMENTAL PROTECTION AGENCY; JAMES PAYNE, *in his Official Capacity as Acting Administrator of the U.S. Environmental Protection Agency*; U.S. DEPARTMENT OF HOMELAND SECURITY; KRISTI NOEM, i*n her Capacity as Secretary of the U.S. Department of Homeland Security*; U.S. DEPARTMENT OF JUSTICE; JAMES R. McHENRY III, *in his Official Capacity as Acting Attorney General of the U.S. Department of Justice*; THE NATIONAL SCIENCE FOUNDATION; and DR. SETHURAMAN PANCHANATHAN, *in his Capacity as Director of the National Science Foundation*, Defendants.	)

ORDER

The Plaintiff States' Motion for Enforcement of the Temporary Restraining Order ("TRO") (ECF No. 66) is GRANTED.

> [It is a] basic proposition that ***all orders and judgments of courts must be complied with promptly***. * * * Persons who make private determinations of the law and refuse to obey an order generally risk criminal contempt even if the order is ultimately ruled incorrect. The orderly and expeditious administration of justice by the courts requires that an order issued by a court with jurisdiction over the subject matter

> and person must be obeyed by the parties until it is reversed by orderly and proper proceedings.

Maness v. Meyers, 419 U.S. 449, 458–59 (1975) (citations and quotations omitted) (emphasis added). The Defendants issued a broad, categorical, all-encompassing directive freezing federal funding. The plain language of the TRO entered in this case prohibits all categorical pauses or freezes in obligations or disbursements based on the OMB Directive or based on the President's 2025 Executive Orders.[1] The Defendants received notice of the TRO, the Order is clear and unambiguous, and there are no impediments to the Defendants' compliance with the Order.

The States have presented evidence in this motion that the Defendants in some cases have continued to improperly freeze federal funds and refused to resume disbursement of appropriated federal funds. *See* Exhibits A-C of the States' motion, (ECF Nos. 66-1, 66-2, and 66-3). The Defendants now plea that they are just trying to root out fraud. *See* ECF No. 70. But the freezes in effect now were a result of the broad categorical order, not a specific finding of possible fraud. The broad categorical and sweeping freeze of federal funds is, as the Court found, likely unconstitutional and has caused and continues to cause irreparable harm to a vast portion of this country. These pauses in funding violate the plain text of the TRO.[2] In response to

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[1] The Defendants acknowledged that they understood what the TRO required: "Federal agencies cannot pause, freeze, impede, block, cancel, or terminate any awards or obligations on the basis of the OMB Memo, *or on the basis of the President's recently issued Executive Orders*." ECF No. 51-1 at 1 (emphasis added).

[2] The Court disagrees with the Defendants' Notice (ECF No. 51), particularly paragraph 2. The Court's TRO is clear and unambiguous in its scope and effect, which is inconsistent with the Defendant's interpretation contained in the Notice. ECF No. 51 at 2.

the Defendants' arguments, they can request targeted relief from the TRO from this Court where they can show a specific instance where they are acting in compliance with this Order but otherwise withholding funds due to specific authority.

Therefore, consistent with the United States Constitution, United States statutes, United States Supreme Court precedent, and the TRO, the Defendants are hereby further **ORDERED** as follows:

1. The Defendants must immediately restore frozen funding during the pendency of the TRO until the Court hears and decides the Preliminary Injunction request.

2. The Defendants must immediately end any federal funding pause during the pendency of the TRO.

3. The Defendants must immediately take every step necessary to effectuate the TRO, including clearing any administrative, operational, or technical hurdles to implementation.

4. The Defendants must comply with the plain text of the TRO not to pause any funds based on pronouncements pausing funding incorporated into the OMB Directive, like Section 7(a) of the *Unleashing* Executive Order, and the OMB *Unleashing* Guidance. The TRO requirements include any pause or freeze included in the *Unleashing* Guidance.

5. The Defendants must immediately restore withheld funds, including those federal funds appropriated in the Inflation Reduction Act and the

Infrastructure Improvement and Jobs Act. The directives in OMB M-25-11 are included in the TRO.

6. The Defendants must resume the funding of institutes and other agencies of the Defendants (for example the National Institute for Health) that are included in the scope of the Court's TRO.

IT IS SO ORDERED.

/s/John J. McConnell, Jr.

John J. McConnell, Jr.
Chief Judge
United States District Court for the District of Rhode Island

February 10, 2025

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
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

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.*, Plaintiffs, v. NATIONAL INSTITUTE OF HEALTH, *et al.*, Defendant[s].	Civil Action No. 25-CV-10338-AK

ORDER GRANTING PLAINTIFF STATES' *EX PARTE* EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER

ANGEL KELLEY, D.J.

Plaintiff States' *Ex Parte* Emergency Motion For Temporary Restraining Order [Dkt. 4] is **GRANTED**. Defendants and their officers, employees, servants, agents, appointees, and successors are hereby enjoined from taking any steps to implement, apply, or enforce the Rate Change Notice (NOT-OD-25- 068) within Plaintiff States until further order is issued by this Court. Counsel for Defendants shall file a status report with the Court within 24 hours of the entry of this Order, and at biweekly intervals thereafter, confirming the regular disbursement and obligation of federal financial assistance funds and reporting all steps that NIH, HHS and their officers, employees, servants, agents, appointees, and successors have taken to comply with the Court's temporary restraining order.

Defendants' opposition to the Motion is due by **Friday, February 14, 2025**. Plaintiff States may file a reply brief, limited to ten pages in length, by **Tuesday, February 18, 2025**. Counsel shall appear in-person for a hearing on the Motion at **10:00 AM** on **Friday, February**

21, 2025. Counsel for the Plaintiff States shall provide a copy of this Order, along with copies of the motion papers, to the following by **6:00 PM** today: Brad P. Rosenberg, Special Counsel, Federal Programs Branch, Civil Division, U.S. Department of Justice; Leah Foley, U.S. Attorney for the District of Massachusetts; and the Chief of the Civil Division of the U.S. Attorneys Office for the District of Massachusetts. Electronic service suffices.

This Temporary Restraining Order shall become effective immediately upon entry by this Court. It shall remain in effect until further order of this Court.

SO ORDERED.

Dated: February 10, 2025

/s/ Angel Kelley
Hon. Angel Kelley
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF RHODE ISLAND; STATE OF NEW JERSEY; COMMONWEALTH OF MASSACHUSETTS; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; THE DISTRICT OF COLUMBIA; STATE OF HAWAI'I; STATE OF MAINE; STATE OF MARYLAND; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NORTH CAROLINA; STATE OF NEW MEXICO; STATE OF OREGON; STATE OF VERMONT; STATE OF WASHINGTON; and STATE OF WISCONSIN,

Plaintiffs,

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C.A. No. 25-cv-39-JJM-PAS

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TEMPORARY RESTRAINING ORDER

The legal standard for a Temporary Restraining Order ("TRO") mirrors that of a preliminary injunction. The Plaintiff States must show that weighing these four factors favors granting a TRO:

1. likelihood of success on the merits;
2. potential for irreparable injury;
3. balance of the relevant equities; and

4. effect on the public interest if the Court grants or denies the TRO.

Planned Parenthood League v. Bellotti, 641 F.2d 1006, 1009 (1st Cir. 1981). The traditional equity doctrine that preliminary injunctive relief is an extraordinary and drastic remedy that is never awarded as of right guides the Court. *Id.* The Court is also fully aware of the judiciary's role as one of the three independent branches of government, and that the doctrine of separation of powers restricts its reach into the Executive Branch. The Court now turns to the four factors.

Likelihood of Success on the Merits

We begin with what courts have called a key factor—a consideration of the movant's likelihood of success on the merits.

In **Count I**, the States allege that the Executive's actions by the Office of Management and Budget ("OMB")[1] violate the Administrative Procedure Act ("APA")[2] because Congress has not delegated any unilateral authority to the Executive to indefinitely pause all federal financial assistance without considering the statutory and contractual terms governing these billions of dollars of grants.

In **Count II**, the States allege that the Executive's actions violate the APA because the failure to spend funds appropriated by Congress is arbitrary and capricious in multiple respects.

[1] See *supra* for discussion of mootness.
[2] 5 U.S.C. § 551 et seq.

In Count III, the States allege that the failure to spend funds appropriated by Congress violates the separation of powers because the Executive has overridden Congress' judgments by refusing to disburse already-allocated funding for many federal grant programs.

In Count IV, the States allege a violation of the Spending Clause of the U.S. Constitution. U.S. Const. art. I, § 8, cl. law 1.

And in Count V, the States allege a violation of the presentment (U.S. Const. art. I, § 7, cl. 2), appropriations (U.S. Const. art. I, § 7), and take care clauses (U.S. Const. art. II, § 3, cl. 3) (the Executive must "take care that the laws be faithfully executed . . .").

Because of the breadth and ambiguity of the "pause," the Court must consider the States' TRO motion today based on the effect it will have on many—but perhaps not all—grants and programs it is intended to cover. Are there some aspects of the pause that might be legal and appropriate constitutionally for the Executive to take? The Court imagines there are, but it is equally sure that there are many instances in the Executive Orders' wide-ranging, all-encompassing, and ambiguous "pause" of critical funding that are not. The Court must act in these early stages of the litigation under the "worst case scenario" because the breadth and ambiguity of the Executive's action makes it impossible to do otherwise.

The Court finds that, based on the evidence before it now, some of which is set forth below, the States are likely to succeed on the merits of some, if not all, their claims. The reasons are as follows:

- The Executive's action unilaterally suspends the payment of federal funds to the States and others simply by choosing to do so, no matter the authorizing or appropriating statute, the regulatory regime, or the terms of the grant itself. The Executive cites no legal authority allowing it to do so; indeed, no federal law would authorize the Executive's unilateral action here.
- Congress has instructed the Executive to provide funding to States based on stated statutory factors—for example, population or the expenditure of qualifying State funds. By trying to impose certain conditions on this funding, the Executive has acted contrary to law and in violation of the APA.
- The Executive Orders threaten the States' ability to conduct essential activities and gave the States and others less than 24 hours' notice of this arbitrary pause, preventing them from making other plans or strategizing how they would continue to function without these promised funds.
- Congress appropriated many of these funds, and the Executive's refusal to disburse them is contrary to congressional intent and directive and thus arbitrary and capricious.
- Congress has not given the Executive limitless power to broadly and indefinitely pause all funds that it has expressly directed to specific recipients and purposes and therefore the Executive's actions violate the separation of powers.

Judge Bruce M. Selya of the First Circuit succinctly set out the black letter law about appropriated funds and Executive powers:

> When an executive agency administers a federal statute, the agency's power to act is "authoritatively prescribed by Congress." *City of Arlington v. FCC*, 569 U.S. 290, 297, 133 S. Ct. 1863, 185 L. Ed. 2d 941 (2013). It is no exaggeration to say that "an agency literally has no power to act ... unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374, 106 S. Ct. 1890, 90 L. Ed. 2d 369 (1986). Any action that an agency takes outside the bounds of its statutory authority is ultra vires, see *City of Arlington*, 569 U.S. at 297, 133 S. Ct. 1863, and violates the Administrative Procedure Act, see 5 U.S.C. § 706(2)(C).

City of Providence v. Barr, 954 F.3d 23, 31 (1st Cir. 2020).

The Executive's statement that the Executive Branch has a duty "to align Federal spending and action with the will of the American people *as expressed through Presidential priorities*," (ECF No. 48-1 at 11) (emphasis added) is a constitutionally flawed statement. The Executive Branch has a duty to align federal spending and action with the will of the people as ***expressed through congressional appropriations,*** not through "Presidential priorities." U.S. Const. art. II, § 3, cl. 3 (establishing that the Executive must "take care that the laws be faithfully executed . . ."). Federal law specifies how the Executive should act if it believes that appropriations are inconsistent with the President's priorities–it must ask Congress, not act unilaterally. The Impoundment Control Act of 1974 specifies that the President may ask that Congress rescind appropriated funds.[3] Here, there is no evidence that the Executive has followed the law by notifying Congress and thereby effectuating a potentially legally permitted so-called "pause."

[3] If both the Senate and the House of Representatives have not approved a rescission proposal (by passing legislation) within forty-five days of continuous session, any funds the Executive is withholding must be made available for obligation.

Justice Brett Kavanaugh wrote when he was on the D.C. Circuit:

> Like the Commission here, a President sometimes has policy reasons (as distinct from constitutional reasons, *cf. infra* note 3) for wanting to spend less than the full amount appropriated by Congress for a particular project or program. But in those circumstances, even the President does not have unilateral authority to refuse to spend the funds. Instead, the President must propose the rescission of funds, and Congress then may decide whether to approve a rescission bill. *See* 2 U.S.C. § 683; *see also Train v. City of New York,* 420 U.S. 35, 95 S. Ct. 839, 43 L. Ed. 2d 1 (1975); Memorandum from William H. Rehnquist, Assistant Attorney General, Office of Legal Counsel, to Edward L. Morgan, Deputy Counsel to the President (Dec. 1, 1969), *reprinted in Executive Impoundment of Appropriated Funds: Hearings Before the Subcomm. on Separation of Powers of the S. Comm. on the Judiciary,* 92d Cong. 279, 282 (1971) ("With respect to the suggestion that the President has a constitutional power to decline to spend appropriated funds, we must conclude that existence of such a broad power is supported by neither reason nor precedent.")

In re Aiken Cnty., 725 F.3d 255, 261, n.1 (D.C. Cir. 2013).

The Court finds that the record now before it substantiates the likelihood of a successful claim that the Executive's actions violate the Constitution and statutes of the United States.

The Court now moves on to the remaining three injunction considerations.

Irreparable Harm

The States have put forth sufficient evidence at this stage that they will likely suffer severe and irreparable harm if the Court denies their request to enjoin enforcement of the funding pause.

- All the States rely on federal funds to provide and maintain vital programs and services and have introduced evidence that the withholding of federal funds

will cause severe disruption in their ability to administer such vital services–even if it is for a brief time.

- The States detail many examples of where the Executive's overarching pause on funding that Congress has allocated will harm them and their citizens. These programs range from highway planning and construction, childcare, veteran nursing care funding, special education grants, and state health departments, who receive billions of dollars to run programs that maintain functional health systems. *See, e.g.*, ECF No. 3-1 at 56 (highway construction programs in Delaware), at 73 (childcare programs in Michigan), at 113 (veterans nursing care funding in Washington state), at 77 (special education programs in Minnesota), and at 100–01 (health care programs in New Mexico).
- The pause in federal funding will also hurt current disaster relief efforts. The States assert that the pause applies to federal actions directing federal financial assistance to North Carolina to address the damage inflicted by Hurricane Helene and to any Federal Emergency Management Agency grant money not yet disbursed, including key support for California's ongoing response to the fires. ECF No. 1 ¶¶ 80–81.
- A January 28, 2025, email from Shannon Kelly, the Director of the National High Intensity Drug Case Trafficking Areas (HIDTA) program, who aids law enforcement in high drug-trafficking areas, shows that payments to state-based HIDTA programs have been paused, putting the public's safety at risk. *Id.* ¶ 83.

The States have set forth facts showing that the Executive's abrupt "pause" in potentially trillions of dollars of federal funding will cause a ripple effect that would directly impact the States and other's ability to provide and administer vital services and relief to their citizens. Thus, the federal grants to States and others that are impounded through the Executive's pause in disbursement will cause irreparable harm.

And it is more than monetary harm that is at stake here. As Justice Anthony Kennedy reminds us, "Liberty is always at stake when one or more of the branches seek to transgress the separation of powers." *Clinton v. City of New York*, 524 U.S. 417, 449–50 (1998) (Kennedy, J. concurring)

Balance of the Equities and Public Interest

As the Court considers the final two factors, the record shows that the balance of equities weighs heavily in favor of granting the States' TRO.

- If the Defendants are prevented from enforcing the directive contained in the OMB Directive, they merely would have to disburse funds that Congress has appropriated to the States and others.
- On the other hand, if the Court denies the TRO, the funding that the States and others are presumably due under law is in an indefinite limbo—a hardship worsened by the fact that the States had less than 24 hours' notice to act in anticipation of the funding shortfall.
- The fact that the States have shown a likelihood of success on the merits strongly suggests that a TRO would serve the public interest. Moreover, the

public interest further favors a TRO because absent such an order, there is a substantial risk that the States and its citizens will face a significant disruption in health, education, and other public services that are integral to their daily lives due to this pause in federal funding.

The evidence in the record at this point shows that, despite the rescission of the OMB Directive, the Executive's decision to pause appropriated federal funds "remains in full force and effect." ECF No. 44.

Mootness

The Defendants now claim that this matter is moot because it rescinded the OMB Directive. But the evidence shows that the alleged rescission of the OMB Directive was in name-only and may have been issued simply to defeat the jurisdiction of the courts. The substantive effect of the directive carries on.

Messaging from the White House and agencies proves the point. At 2:04 EST, less than an hour before the Court's hearing on the States' motion on Wednesday, the Defendants filed a Notice saying, "OMB elected to rescind that challenged Memorandum. *See* OMB Mem. M-25-14, *Rescission of M-25-13* (Jan. 28, 2025) ('OMB Memorandum M-25-13 is rescinded.')." ECF No. 43. Yet about twenty minutes before the Defendants filed the Notice, the President's Press Secretary sent a statement via the X platform that said: "The President's [Executive Orders] EO's on federal funding remain in full force and effect and will be rigorously implemented." ECF No. 44. And then the following day (January 30, 2025 at 7:50 MST and again at 5:27 p.m. EST) after the so-called rescission, the Environmental Protection Agency, in an email to

federal grant recipients, said that the awarded money could not be disbursed while it worked "diligently to implement the [OMB] Memorandum, Temporary Pause of Agency Grant, Loan, and Other Financial Assistance Programs, to align Federal spending and action with the will of the American people as expressed through President Trump's priorities. The agency is temporarily pausing all activities related to the obligation or disbursement of EPA Federal financial assistance at this time. EPA is continuing to work with OMB as they review processes, policies, and programs, as required by the memorandum." ECF No. 48-1 at 6, 11.

Based on the Press Secretary's unequivocal statement and the continued actions of Executive agencies, the Court finds that the policies in the OMB Directive that the States challenge here are still in full force and effect and thus the issues presented in the States' TRO motion are not moot.

Conclusion

Consistent with the findings above, and to keep the status quo, the Court hereby ORDERS that a TEMPORARY RESTRAINING ORDER is entered in this case until this Court rules on the States' forthcoming motion for a preliminary injunction, which the States shall file expeditiously.

During the pendency of the Temporary Restraining Order, Defendants shall not pause, freeze, impede, block, cancel, or terminate Defendants' compliance with awards and obligations to provide federal financial assistance to the States, and Defendants shall not impede the States' access to such awards and obligations, except on the basis of the applicable authorizing statutes, regulations, and terms.

If Defendants engage in the "identif[ication] and review" of federal financial assistance programs, as identified in the OMB Directive, such exercise shall not affect a pause, freeze, impediment, block, cancellation, or termination of Defendants' compliance with such awards and obligations, except on the basis of the applicable authorizing statutes, regulations, and terms.

Defendants shall also be restrained and prohibited from reissuing, adopting, implementing, or otherwise giving effect to the OMB Directive under any other name or title or through any other Defendants (or agency supervised, administered, or controlled by any Defendant), such as the continued implementation identified by the White House Press Secretary's statement of January 29, 2025. ECF No. 44.

Defendants' attorneys shall provide written notice of this Order to all Defendants and agencies and their employees, contractors, and grantees by Monday, February 3, 2025, at 9 a.m. Defendants shall file a copy of the notice on the docket at the same time.

Defendants shall comply with all notice and procedural requirements in the award, agreement, or other instrument relating to decisions to stop, delay, or otherwise withhold federal financial assistance programs.

The TRO shall be in effect until further Order of this Court. A preliminary hearing, at which time the States will have to produce specific evidence in support of a preliminary injunction, will be set shortly at a day and time that is convenient to the parties and the Court.

IT IS SO ORDERED.

s/John J. McConnell, Jr.

John J. McConnell, Jr.
Chief Judge
United States District Court for the District of Rhode Island

January 31, 2025

From:	Erin Fitzgerald
To:	Bhattacharya, Jayanta (NIH/OD) [E]; Memoli, Matthew (NIH/OD) [E]; Glassman, Ilene (NIH/NIGMS) [E]; Stamm, Joyce (NIH/NIGMS) [E]; NIH Executive Secretariat
Cc:	Ellen Fisher; Cristina Takacs; Om Perumal; Ariadna Vazquez; UNM Office of Sponsored Projects
Subject:	[EXTERNAL] Appeal to Termination - 5T34GM145428-03, U-Rise, Cristina Takacs, University of New Mexico
Date:	Wednesday, April 30, 2025 5:42:28 PM
Attachments:	NIH_NIGMS_T34GM145428_CTakacs_URISE_FINAL_FE2.pdf

Dear Drs. Jay Bhattacharya & Matthew Memoli,

On behalf of the University of New Mexico and our Principal Investigator, Cristina Takacs, I am submitting a request to appeal the decision to terminate grant 5T34GM145428-03, “U-Rise at the University of New Mexico.” The decision to terminate this grant was received by the University of New Mexico on April 2, 2025, with an effective date as of March 31,2025.

Enclosed please find a letter detailing the appeal, the termination noticed dated April 2, 2025 and Program Plan associated with this project.

I submit this request as an Authorized Organizational Representative (AOR) at the University of New Mexico.

Please confirm receipt of this message.

Thank you,

ERIN FITZGERALD, MBA, CRA | Associate Director, UNM Office of Sponsored Projects | 505-277-2665

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

April 30, 2025

Via Email: jayanta.bhattacharya@nih.hhs.gov

The Honorable Jay Bhattacharya, MD, PhD, Director
National Institutes of Health (NIH)
110 Irving Street NW
Washington, DC 20010

RE: Appeal of Termination, Project Number 5T34GM145428-03

Dear Director Bhattacharya:

This letter serves as our appeal of the termination of grant award 5T34GM145428-03. As referenced in the attached letter (Exhibit A) dated April 2, termination is premised on the award "*no longer effectuating agency priorities*". **We strongly disagree.** Continued training of these students in biomedical science directly supports the Administration's goal to restore American leadership in science and technology[1] and to ensure the United States remains the "world's premier hub" for scientific and technology breakthroughs. It also effectuates the Administration's goals of "making America healthy"[2] by advancing education and research towards innovative medical cures.

In addition, the termination letter states that "*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.*" **This statement does not reflect the UNM U-RISE program.** The UNM U-RISE program is a training program for Honors students, regardless of their background. Our selection criteria are based on merit, a student's academic success and their desire to conduct biomedical research. Consequently, approximately half of our participants are white, 60% are female and their GPAs average 3.8 (range=3.3-4.2). We purposefully recruited UNM's best students and our trainee diversity reflected the ethnic and gender composition of our student body, which is reflective of the State's demographics. It is also important to note that UNM students who have participated in NIH Undergraduate Research Initiative for Student Enhancement (U-RISE) training grants have a 100% graduation rate within 5 years, even higher than the 96% graduation rate for such scholars nationwide.

[1] Fact Sheet: President Donald J. Trump Launches PCAST to Restore American Leadership in Science and Technology – The White House
[2] Establishing the President's Make America Healthy Again Commission – The White House

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

The U-RISE program represents the primary means of fostering undergraduate research at UNM. The termination of this grant not only limits the research opportunities and graduation rates for undergraduate students but also impacts the supply of critical biomedical workforce to support the scientific advances, technological innovation, and economic development of the region and the United States.

Currently, only a small percentage (2–4% over the past five years) of all UNM undergraduates go on to earn a Ph.D. in biomedically related science fields. In contrast, during the same period, **87% of students who participated in programs like U-RISE have enrolled in doctoral programs**. This highlights the critical need for continued support of research training programs like U-RISE to drive scientific innovation and strengthen the biomedical workforce to ensure that Administration priorities are met and sustainable for future generations of Americans.

The UNM respectfully requests that the NIH reconsider its decision to terminate this important grant award. Additional information about the UNM U-RISE program is attached in Exhibit B.

Thank you for your consideration of this appeal.

Sincerely,

Ellen R. Fisher, PhD
Vice President of Research
University of New Mexico

Cristina Takacs-Vesbach (Apr 30, 2025 10:01 MDT)

Cristina Takacs, PhD
Principal Investigator
University of New Mexico

Exhibit A: Notice of Grant Termination dated 4/2/2025; effective 3/31/2025
Exhibit B: Program Plan

Cc: Dr. Matthew Memoli, memolimj@nih.hhs.gov

Erin M. Fitzgerald, MBA CRA
Authorized Organizational Representative (AOR)
University of New Mexico

Exhibit A

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

Rebecca Valdez
UNIVERSITY OF NEW MEXICO
rvaldez3@unm.edu

Dear Rebecca Valdez,

Funding for Project Number **5T34GM145428-03** 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).

From: Bulls, Michelle G. (NIH/OD) [E]
To: Louie, Sharon
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 10:21:20 AM
Attachments: image002.png

This Message Is From an External Sender
This message came from outside your organization.

3/21/2025

Sharon Louie
University Of California, San Francisco
sharon.louie@ucsf.edu

Dear Sharon Louie:

Effective with the date of this letter, funding for Project Number 1R01HD112464-01A1 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 9/21/2024, 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 [6]

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.

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)

From: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>
Sent: Friday, March 21, 2025 9:08 PM
To: Foster, Diana Greene <DianaGreene.Foster@ucsf.edu>
Subject: RE: Grant Termination Notification; - A144674 - 1R01HD112464-01A1
Importance: High

This Message Is From an External Sender

This message came from outside your organization.

Hi Diana,

Thanks for forwarding the letter. I also realized after I sent the request that it was in the email below.

I am very confused. As you know, I'd been working with Debbie on getting the budget fixed for this award, and we had just released your revised NoA on 3/20. It must have been very jarring to then receive this today. As part of the review process for issuing that revised NoA, I was required to review your project to confirm that it aligned with FY2025 goals. This process has changed over time, but when I did the review for your project (several weeks ago), we were asked to complete a form indicating whether the project was focused on any of the areas that have been identified as low program priority, which include gender identity, DEI, or environmental justice. Thus, there is a record in your grant folder from just a few weeks ago *confirming* that your project is aligned with FY 2025 goals and is not research focused on gender identity.

However, as I mentioned earlier, I was not consulted about this termination. Moreover, scientific program staff at NICHD have no information about how awards are being identified for potential termination, what criteria are being used, or who is involved in making these decisions. Hence, I do not know how unnamed people erroneously determined that this project is focused on gender identity, that "no corrective action is possible," or that the "premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Had the people involved in this decision consulted my expert assessment as the scientist managing this award, they would have known it was aligned with FY2025 goals.

I am very sorry and I hope that this error can be cleared up on appeal. Please let me know if you have additional questions.

Thanks,

Ronna

Ronna Popkin, PhD
Program Officer
National Institutes of Health
Department of Health and Human Services
Office Phone: 301-827-5121

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:34 AM
To: Madison Spiva <mspiva@uci.edu>
Subject: Grant Termination Notification

3/21/2025

Maria G. Diaz
University Of California-Irvine
mspiva@uci.edu

Dear Maria G. Diaz:

Effective with the date of this letter, funding for Project Number 5DP2AI164315-04 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 9/1/2023, 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."

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 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)

UCSF
University of California
San Francisco

Winona L. Ward, CRA
Assistant Vice Chancellor
Office of Sponsored Research

Office of the Executive
Vice Chancellor and Provost
UCSF Campus Box 0962
San Francisco, CA 94143

winona.ward@ucsf.edu

www.ucsf.edu

April 15, 2025

Dr. Matthew Memoli
Acting Director
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Subject: Appeal of Early NIH Termination Notice for 5R01DA052016-04, Substance use and DNA methylation at the intersection of sex and gender

Dear Dr. Memoli,

On behalf of Dr. Annesa Flentje and the University of California San Francisco (UCSF), we want to thank the NIH for the tremendous amount of support for the UCSF research mission and the subject research project. UCSF shares the NIH mission to improve the health of Americans, extend life, and reduce illness by conducting research to better understand the impacts of substance use on the biology (epigenome) of humans, and to develop biological metrics for better measuring the accumulation of substance use exposure. We aim to develop tools to better measure, diagnose, and ultimately treat substance use disorders to help Americans experiencing problems with substance use.

In accordance with the 2024 Policy Statement 8.7[1], we are writing to exercise our first level appeal rights to request a review in response to the Termination Notice issued March 20, 2025, for 5R01DA052016-04. This request is submitted within the 30-day timeframe to request a review.[2]

We acknowledge the notice of termination which includes the following statement: *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.*

We respectfully object to the subject grant termination on the grounds that:
1. **Completing our work could have considerable scientific impact and return on investment.** The termination focused on the unscientific nature of gender identity, but gender identity is not the focus of the work that was terminated. Our remaining work is to report the results of epigenetic markers of substance use.

[1] https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.7_grant_appeals_procedures.htm
[2] https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200#200.342 and 42 CFR 50.406(a)

a. Progress to date: We collected whole blood specimens from 611 participants, carefully selected from >12,000 people in a longitudinal national cohort study. We completed DNA isolation and methyl capture sequencing of these samples. We characterized participants' substance use and classified participants into substance use groups based on up to 7 years of substance use data
b. Preliminary results: We conducted preliminary analyses among our sample and found evidence for overrepresentation of differential methylation within eight Reactome pathways[1] comparing people who used cannabis (*n*=116) versus people who don't use substances (*n*=219). In our preliminary analysis we saw that pathways that evidenced differential methylation based on cannabis use exposure included pathways relevant to neuronal systems (*i.e.,* Neuronal system, Transmission across chemical synapses), signal transduction (*i.e.,* GPCR downstream signaling, G alpha (i) signaling events, G-protein mediated events, PLC beta mediated events), metabolism (*i.e.,* Integration of energy metabolism), and opioid receptors[2,3] (*i.e.,* Opioid signaling).
c. Current status: When we received the termination notice we were in the process of refining the data processing pipeline for the methylation data and completing analyses for all of our substance use groups.
Summary: Reinstatement of our award would allow us to complete our analysis and publish our results examining differential methylation for cannabis exposure and other substance use groups (*i.e.,* stimulant use, alcohol and tobacco use, opioid use, poly substance use, inhaled nitrate use) and to identify if these targets are contingent on biological responses by sex.

2. **Potential Impact:** Our study will shed light on new methylation targets that may explain biological changes associated with substance use exposure. This may allow us to develop new treatments for substance use disorders or better understand the mechanisms by which substance use exposure alters other health outcomes.
3. **Reduced Harm to Participants:** Our longitudinal cohort study commits to participants that they will receive a return on their results. For this study, 611 participants committed time and effort to receive a return on research results. Our own qualitative interviews with our participants (conducted in a now completed supplement to this project) concluded that participants primary motivation for providing biospecimens for substance use research was to contribute to research knowledge about them. Our participants received large biospecimen coolers in the mail, then made appointments at local laboratories, and carried these large boxes to these laboratories (frequently carrying them significant distances or on public transportation), for eventual shipment back to our labs. We have an ethical duty to complete our work to return results to our participants.

This request includes supporting documents, as follows:
1. A copy of the adverse determination (termination letter)
2. A copy of Revised Notice of Award for 5R01DA052016-04
3. A copy of Table 1. Preliminary data
4. Total amount in dispute

Request for Review:
We respectfully request that NIH reconsider its decision to terminate this award and provide a fair opportunity to demonstrate our commitment to the project's success. We appreciate NIH's support of UCSF's research programs and look forward to a favorable response.

If you have any questions or require additional information, please do not hesitate to ask.

Sincerely,

Signed by:
7B60265FA93B41F...
Annesa Flentje, PhD
Professor

DocuSigned by:
D883E139BF09463...
Winona Ward
Assistant Vice Chancellor
Office of Sponsored Research | Office of Clinical Trial Activation

Attachments
Cc:
Dr. Harold Collard, UCSF Vice Chancellor of Research
Dr. Laura Wagner, PhD, RN, FAAN, Community Health Systems
Dr. Carol Dawson-Rose, PhD, RN, FAAN, Dean and Styles Professor of Nursing
Associate Vice Chancellor for Nursing Affairs

03/20/2025

Magdalene Cho
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
cgrasteam@ucsf.edu

Dear Magdalene Cho:

Effective with the date of this letter, funding for Project Number 5R01DA052016-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Pamela Fleming, Chief Grants Management Officer, National Institute on Drug Abuse
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Notice of Award
FAIN# R01DA052016
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425
SAN FRANCISCO, CA 94103

2. Congressional District of Recipient
11

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
Annesa Flentje, PHD
Assistant Professor
annesa.flentje@ucsf.edu
415-502-0697

8. Authorized Official
Magdalene Cho
maggie.cho@ucsf.edu
415-502-8752

Federal Agency Information

9. Awarding Agency Contact Information
Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE
pfleming@mail.nih.gov
301-480-1159

10. Program Official Contact Information
Amy C Lossie

NATIONAL INSTITUTE ON DRUG ABUSE
amy.lossie@nih.gov
301-827-6092

Federal Award Information

11. Award Number
5R01DA052016-04

12. Unique Federal Award Identification Number (FAIN)
R01DA052016

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Substance use and DNA methylation at the intersection of sex and gender

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction 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 08/01/2023 **– 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	$471,375
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$471,375
26. Project Period Start Date 09/30/2020 **– End Date** 03/20/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,927,036

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Pamela G. Fleming

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 5R01DA052016-04 REVISED

Principal Investigator(s):
Annesa Flentje, 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 Drug Abuse of the National Institutes of Health under Award Number R01DA052016. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$107,503
Fringe Benefits	$45,642

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:01 AM

Personnel Costs (Subtotal)	$153,145
Materials & Supplies	$45,000
Travel	$4,500
Other	$1,392
Subawards/Consortium/Contractual Costs	$135,867
Publication Costs	$3,708
Federal Direct Costs	$343,612
Federal F&A Costs	$127,763
Approved Budget	$471,375
Total Amount of Federal Funds Authorized (Federal Share)	$471,375
TOTAL FEDERAL AWARD AMOUNT	$471,375
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (4) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01DA052016-04	$471,375
3R01DA052016-04S1	$164,083
TOTAL	**$635,458**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$471,375	$635,458

Fiscal Information:
Payment System Identifier: 1946036493A6
Document Number: RDA052016A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
OD	8055781	$56,152
DA	8472629	$415,223

NIH Administrative Data:
PCC: GE/ACL / **OC**: 41025 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:01:41 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01DA052016-04 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 – 5R01DA052016-04 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).

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) R01DA052016. 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*

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:01 AM

reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Office Of The Director, National Institutes Of Health (OD) National Institute On Drug Abuse (NIDA)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DA SPECIFIC AWARD CONDITIONS – 5R01DA052016-04 REVISED

Clinical Trial Indicator: No

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:01 AM

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 #2 - TERMINATION

It is the policy of NIH not to further prioritize research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. 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 closeout process, will need to submit the necessary closeout documents (i.e. Final Research Performance Program Report (F-RPPR), Final Invention Statement (FIS), and the Final Federal Financial Report (FFR)) within 120 days of the end date of this grant to avoid unilateral closeout.

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

This revision supersedes Notice of Award (NoA) issued 8/28/2024.

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REVISION #1 - COFUNDING

This award is revised to cite the co-funding by the NIH, Office of Research on Women's Health (ORWH) and the National Institute on Drug Abuse (NIDA). All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented must include a formal acknowledgement of the ORWH/NIDA support, citing the NIDA grant number as identified on this award document.

This revision supersedes Notice of Award (NoA) issued 7/20/2023. All other terms below remain applicable.

_____

NOFO REQUIREMENTS

This award is subject to the requirements detailed in RFA-OD-19-029, entitled "The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional)", posted on 09/27/19, which is incorporated by reference as terms and conditions of this award.

The FOA is available here: https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-19-029.html

GENOMIC DATA SHARING

Dissemination of study data will be in accord with the recipient's accepted genomic data sharing (GDS) plan as stated on page 142 of the application submitted on 11/22/2019. Failure to adhere to the sharing plan as mutually agreed upon by the recipient and NIDA may result in enforcement actions as described in the NIH Grants Policy Statement.

NIDA TERMS

In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:01 AM

release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01DA052016-04 REVISED

INSTITUTION: The Regents of the UCSF

Budget	Year 4
Salaries and Wages	$107,503
Fringe Benefits	$45,642
Personnel Costs (Subtotal)	$153,145
Materials & Supplies	$45,000
Travel	$4,500
Other	$1,392
Subawards/Consortium/Contractual Costs	$135,867
Publication Costs	$3,708
TOTAL FEDERAL DC	$343,612
TOTAL FEDERAL F&A	$127,763
TOTAL COST	$471,375

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	61.5%
F&A Cost Base 1	$207,745
F&A Costs 1	$127,763

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/22/2025 12:01 AM

Table 1. Longitudinal sample from which N = 611 participants were selected to provide blood specimens

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	20	18	0	15	6	2	0	0	0	61
Asian	223	128	10	5	4	0	0	0	0	370
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	186	116	9	14	13	0	0	0	0	338
White	6549	3259	192	280	109	5	0	0	0	10394
More than One Race	479	180	14	71	36	2	0	0	0	782
Unknown or Not Reported	72	43	7	186	158	8	1	0	23	498
Total	7529	3744	232	571	326	17	1	0	23	12443

Table 2. Substance use categories of N= 611 individuals who provided biospecimens

Classification of longitudinal substance use, *n*	Male	Female
Little to no substance use, 219	73	146
Cannabis use, 116	40	76
Stimulant use, 93	21	72
Alcohol and tobacco use, 75	30	45
Opioid use, 38	14	24
Polysubstance use, 36	17	19
Inhaled nitrate use, 34	29	5

Table 1. Longitudinal sample from which N = 611 participants were selected to provide blood specimens

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	20	18	0	15	6	2	0	0	0	61
Asian	223	128	10	5	4	0	0	0	0	370
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	186	116	9	14	13	0	0	0	0	338
White	6549	3259	192	280	109	5	0	0	0	10394
More than One Race	479	180	14	71	36	2	0	0	0	782
Unknown or Not Reported	72	43	7	186	158	8	1	0	23	498
Total	7529	3744	232	571	326	17	1	0	23	12443

Table 2. Substance use categories of N= 611 individuals who provided biospecimens

Classification of longitudinal substance use, *n*	Male	Female
Little to no substance use, 219	73	146
Cannabis use, 116	40	76
Stimulant use, 93	21	72
Alcohol and tobacco use, 75	30	45
Opioid use, 38	14	24
Polysubstance use, 36	17	19
Inhaled nitrate use, 34	29	5

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:35 AM
To: Boultinghouse, Anita Yip <Anita.Yip2@ucsf.edu>
Subject: Grant Termination Notification

This Message Is From an External Sender

This message came from outside your organization.

National Institutes of Health
Office of Extramural Research

3/21/2025

Yip, Anita
University Of California, San Francisco

anita.yip2@ucsf.edu

Dear Yip, Anita:

Effective with the date of this letter, funding for Project Number 3K12AR084219-26S1 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 9/16/2024, 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 Erik Edgerton, Chief Grants Management Officer, NIAMS
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)

National Institutes of Health
Office of Extramural Research

March 14, 2025

Jennifer Scerri
Stanford University
Email: jscerri@stanford.edu

Dear Jennifer Scerri:

Effective with the date of this letter, funding for Project Number OT2 OD025276-03 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 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) 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 *All of Us* Research Program will set up an official meeting 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,

LaMeshia Billington
Other Transaction Agreements Officer
All of Us Research Program

cc: Michelle G. Bulls, Director
Office of Policy for Extramural Research Administration, OER

[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)

Attachment 1

National Institutes of Health
Office of Extramural Research

March 11, 2025

Center for Innovative Public Health Research
Camille Labranche
Authorized Organizational Official
160 Avenida Victoria
San Clemente, CA 92672
Email: camille@innovativepublichealth.org

Dear Camille Labranche

Funding for Project Number 5R01NR020846-02 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 June 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 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]

[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.

no corrective action is possible here. The premise of Project Number 5R01NR020846-02 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 *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: 2025.03.11 23:19:47 -04'00'

Michelle G. Bulls on behalf of Brian Albertini, CGMO – NINR

Director, Office of Policy for Extramural Research Administration, OER

[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).

03/19/2025

Benjamin Wichterman
UNIVERSITY OF MINNESOTA
awards@umn.edu

Dear Benjamin Wichterman:

Effective with the date of this letter, funding for Project Number 5R01CA265945-03 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 Crystal Wolfrey, Chief Grants Management Officer, National Cancer 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)

National Institutes of Health
Office of Extramural Research

March 18, 2025

Olive T. Giovannetti
The Regents of the University of California, San Francisco
Olive.giovannetti@ucsf.edu

Dear Olive T. Giovannetti:

Effective with the date of this letter, funding for Project Number 1R01 AI181732-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 18, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

03/20/2025

Gregory Sorensen
UNIVERSITY OF MARYLAND BALTIMORE
nga@umaryland.edu

Dear Gregory Sorensen:

Effective with the date of this letter, funding for Project Number 5R01DE032225-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 09/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 13:32:12 -04'00'

Michelle G. Bulls, on behalf Gabriel Hidalgo, Chief Grants Management Officer, National Institute of Dental and Craniofacial Research
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 18, 2025

Carol Rhodes
University of Washington
osp@uw.edu

Dear Carol Rhodes:

Effective with the date of this letter, funding for Project Number 1F31 AI181431-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/16/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *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 Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 12, 2025

Carole Rhodes
University of Washington
carhodes@uw.edu

Dear Carol Rhodes :

Funding for Project Number 1G13LM014426-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 15, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Andrea Culhane, Chief Grants Management Officer, NLM
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

Date: March 11, 2025

To: Jennifer Howland, Senior Grant and Contract Officer, University of Minnesota

RE: 1K01MH132899-01A1 *Using Data Science to Quantify the Impact of Misinformation, Mistrust, and Other Key Psychosocial Factors on Vaccine Hesitancy Among Vulnerable People Experiencing Psychopathology*

Ms. Howland:

Funding for Project Number 1K01MH132899-01A1 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 5/31/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 1K01MH132899-01A1 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,

Theresa R. Jarosik -S Digitally signed by Theresa R. Jarosik -S
Date: 2025.03.11 16:11:04 -04'00'

Theresa Jarosik
Chief Grants Management Officer
National Institute of Mental Health

cc:
Michelle G. Bulls, Director, Office of Policy for Extramural Research Administration, Office of Extramural Research (OER)
Michael Bronstein, Ph.D., Principal Investigator, University of Minnesota

[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).

From: Bulls, Michelle G. (NIH/OD) [E]
To: johnsonholte@rsp.wisc.edu
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:00 PM
Attachments: image002.png

3/24/2025

Darlene A Holte
University Of Wisconsin-Madison
johnsonholte@rsp.wisc.edu

Dear Darlene A Holte:

Effective with the date of this letter, funding for Project Number 1P01AI165077-01 is hereby terminated pursuant to the Fiscal Year 2021 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 2021 Policy Statement applies to your project because NIH approved your grant on 9/16/2021, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2021 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations

imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.* [8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# P01AI165077
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
YOSHIHIRO KAWAOKA, DVM
Professor
yoshihiro.kawaoka@wisc.edu
608-265-4925

8. Authorized Official
Brenda Egan
nih@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Elizabeth R. Sihombing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
elizabeth.sihombing@nih.gov
240-669-5530

10. Program Official Contact Information
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
1P01AI165077-01

12. Unique Federal Award Identification Number (FAIN)
P01AI165077

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
PanCorVac (Center for Pan-Coronavirus Vaccine Development)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/16/2021 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$7,000,324
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$7,000,324
26. Project Period Start Date 09/16/2021 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,000,324

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1P01AI165077-01 REVISED

Principal Investigator(s):
YOSHIHIRO KAWAOKA, DVM

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number P01AI165077. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
Federal Direct Costs	$6,170,370
Federal F&A Costs	$829,954
Approved Budget	$7,000,324
Total Amount of Federal Funds Authorized (Federal Share)	$7,000,324
TOTAL FEDERAL AWARD AMOUNT	$7,000,324
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$7,000,324	$7,000,324

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: PAI165077AC6
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
AI	8050485	$7,000,324

NIH Administrative Data:
PCC: M51Q S / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:01:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01AI165077-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P01AI165077-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01AI165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1P01AI165077-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

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

Supersedes previous Notice of Award dated **08/30/2024**. All other terms and conditions still apply to this award.

*****

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the letter dated **07/30/2024**. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

This is the final extension that will be allowed for this project.

Supersedes previous Notice of Award dated **05/26/2023**. All other terms and conditions still apply to this award.

*****

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

REVISED AWARD: This award is revised to remove the requirement to submit an extension application for years four and five of the project period.

This Notice of Award removes carryover authority on this award.

Supersedes previous Notice of Award dated 09/17/2021. All other terms and conditions still apply to this award.

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

The budget period anniversary start date for future year(s) will be **September 1.**

This Notice of Award (NoA) includes funds for activity with **Georgia Tech Research Corporation** in the amount of **$1,404,775** (**$887,974** direct costs + **$516,801** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Chicago** in the amount of **$984,000** (**$600,000** direct costs + **$384,000** F&A costs).

This Notice of Award (NoA) includes funds for activity with **St. Jude Children's Research Hospital** in the amount of **$1,364,994** (**$749,997** direct costs + **$614,997** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$972,246** (**$573,597** direct costs + **$398,649** F&A costs).

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan
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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the **Just-In-Time**. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

BEN-GURION UNIVERSITY OF THE NEGEV, ISRAEL

Duke-NUS Medical School, SINGAPORE

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used. When submitting future Progress Reports indicate at the beginning of the report:

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01AI165077-01 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1
Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
TOTAL FEDERAL DC	$6,170,370
TOTAL FEDERAL F&A	$829,954
TOTAL COST	$7,000,324

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$540,971
F&A Costs 1	$300,239
F&A Cost Rate 2	55.5%
F&A Cost Base 2	$471,971
F&A Costs 2	$261,944
F&A Cost Rate 3	55.5%
F&A Cost Base 3	$482,471
F&A Costs 3	$267,771

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:01 AM

March 12, 2025

Amy Lagowski
Research Foundation for the State University of New York
Amy.Lagowski@buffalo.edu

Dear Amy Lagowski:

Funding for Project Number 1P50MD019473-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 19, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

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

[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).

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI171196
Federal Award Date
04/18/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF DELAWARE
550 S COLLEGE AVE
NEWARK, DE 19713

2. Congressional District of Recipient
00

3. Payment System Identifier (ID)
1516000297A1

4. Employer Identification Number (EIN)
516000297

5. Data Universal Numbering System (DUNS)
059007500

6. Recipient's Unique Entity Identifier
T72NHKM259N3

7. Project Director or Principal Investigator
Karl Robert Schmitz, PHD

schmitzk@udel.edu
302-831-6100

8. Authorized Official
Laura V Paller
lpaller@udel.edu
302-831-1470

Federal Agency Information

9. Awarding Agency Contact Information
KATHERINE ANNE Matheson

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
katherine.matheson@nih.gov
301-594-4218

10. Program Official Contact Information
Richard Thomas Robinson
Health Scientist Administrator
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
richard.robinson@nih.gov

Federal Award Information

11. Award Number
1R01AI171196-01A1

12. Unique Federal Award Identification Number (FAIN)
R01AI171196

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Phosphoarginine-linked protein quality control and stress responses in mycobacteria

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/15/2024 **– End Date** 06/30/2025	
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	$346,677
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$346,677
26. Project Period Start Date 08/15/2024 **– End Date** 06/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$346,677

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: 4/18/2025 12:05 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 – 1R01AI171196-01A1 REVISED

Principal Investigator(s):
Karl Robert Schmitz, PHD

Award e-mailed to: udelaware-awards@udel.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF DELAWARE 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 R01AI171196. 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: 4/18/2025 12:05 AM

Federal Direct Costs	$225,000
Federal F&A Costs	$121,677
Approved Budget	$346,677
Total Amount of Federal Funds Authorized (Federal Share)	$346,677
TOTAL FEDERAL AWARD AMOUNT	$346,677

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$346,677	$346,677

Fiscal Information:
Payment System Identifier: 1516000297A1
Document Number: RAI171196A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
GM	8012746	$346,677

NIH Administrative Data:
PCC: M33D B / **OC**: 41021 / **Released**: 04/17/2025
Award Processed: 04/18/2025 12:05:21 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI171196-01A1 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 – 1R01AI171196-01A1 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 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: 4/18/2025 12:05 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) R01AI171196. 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.

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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:05 AM

National Institute Of General Medical Sciences (NIGMS)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R01AI171196-01A1 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.

Revised Award: It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed.

UNIVERSITY OF DELAWARE 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:05 AM

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.

Supersedes previous Notice of Award dated 08/16/2024. All other terms and conditions still apply to this award.

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REVISED AWARD: This award is revised to amend an internal Common Accounting Number (CAN). All previous terms and conditions of award remain in effect.

Supersedes previous Notice of Award dated 08/15/2024. All other terms and conditions still apply to this award.
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In accordance with the fiscal year 2024 NIAID Financial Management Plan, NIAID is funding this grant at 90% of the approved budget for the initial budget period. If the final appropriations permit, adjustments may be made to restore funds at or near the requested amount.

The initial budget period has been adjusted to 11 months. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

The budget period anniversary start date for future year(s) will be **July 1**.

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This award is co-funded. Participating ICs and/or agencies are named in Section III of the NoA. All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented must include a formal acknowledgment of NIAID and participating ICs and/or agencies support, citing the NIAID grant number as identified on this award document.

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This is a Modular Award without direct cost categorical breakdowns in accordance with the guidelines published in the NIH Grants Policy Statement, see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_13/13.5_post-award_administration.htm.

Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

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Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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.

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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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). 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: 1R01AI171196-01A1 REVISED

INSTITUTION: UNIVERSITY OF DELAWARE

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:05 AM

Budget	Year 1
TOTAL FEDERAL DC	$225,000
TOTAL FEDERAL F&A	$121,677
TOTAL COST	$346,677

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	60%
F&A Cost Base 1	$202,795
F&A Costs 1	$121,677

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:05 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI173928
Federal Award Date
04/18/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF MINNESOTA
2221 UNIVERSITY AVE SE STE 100
MINNEAPOLIS, MN 55414

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1416007513A5

4. Employer Identification Number (EIN)
416007513

5. Data Universal Numbering System (DUNS)
555917996

6. Recipient's Unique Entity Identifier
KABJZBBJ4B54

7. Project Director or Principal Investigator
Noelle Noyes, DVM

nnoyes@umn.edu
612-624-3562

8. Authorized Official
Brett Carlson
awards@umn.edu
612-626-7441

Federal Agency Information

9. Awarding Agency Contact Information
Sufiyan Saeed
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
sufiyan.saeed@nih.gov
240-627-3761

10. Program Official Contact Information
Inka I Sastalla
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
inka.sastalla@nih.gov
(301) 761-6431

Federal Award Information

11. Award Number
1R01AI173928-01A1

12. Unique Federal Award Identification Number (FAIN)
R01AI173928

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Triple-enriched metagenomics for robust resistome analysis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/15/2024 **– End Date** 02/28/2025	
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	$728,432
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$728,432
26. Project Period Start Date 04/15/2024 **– End Date** 02/28/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$728,432

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.

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 – 1R01AI173928-01A1 REVISED

Principal Investigator(s):
Noelle Noyes, DVM

Award e-mailed to: awards@umn.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MINNESOTA 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 R01AI173928. 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)

Salaries and Wages	$191,859

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

Fringe Benefits	$57,767
Personnel Costs (Subtotal)	$249,626
Materials & Supplies	$83,016
Travel	$2,201
Other	$5,000
Subawards/Consortium/Contractual Costs	$151,102
Publication Costs	$3,500
ADP/Computer Services	$7,342
Equipment or Facility Rental/User Fees	$2,000
Tuition Remission	$16,918
Federal Direct Costs	$520,705
Federal F&A Costs	$207,727
Approved Budget	$728,432
Total Amount of Federal Funds Authorized (Federal Share)	$728,432
TOTAL FEDERAL AWARD AMOUNT	$728,432
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$728,432	$728,432

Fiscal Information:
Payment System Identifier: 1416007513A5
Document Number: RAI173928A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
AI	8023029	$728,432

NIH Administrative Data:
PCC: M63D BR / **OC**: 41021 / **Released**: 04/17/2025
Award Processed: 04/18/2025 12:06:52 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI173928-01A1 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 – 1R01AI173928-01A1 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 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).

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) R01AI173928. 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*.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R01AI173928-01A1 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.

Revised Award: It is the policy of NIH not to prioritize research programs related to 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

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, no additional funding will be awarded for this project, and all future years have been removed.

UNIVERSITY OF MINNESOTA 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.

Supersedes previous Notice of Award dated 05/31/2024. All other terms and conditions still apply to this award.

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REVISED AWARD: The initial budget period has been adjusted to 11 months. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

The budget period anniversary start date for future year(s) will be March 1.

Supersedes previous Notice of Award dated **04/15/2024**. All other terms and conditions still apply to this award.

******

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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

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In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Future budget year(s) committed amounts were adjusted accordingly. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

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This Notice of Award (NoA) includes funds for **University of Florida** in the amount of **$151,102**.

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Research conducted at the following site(s) must be reported in the Research Performance Progress Report (RPPR), Section G.9 (Foreign component):

Dalhousie University - CANADA

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Highly Pathogenic Agents:

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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.

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: 1R01AI173928-01A1 REVISED

INSTITUTION: UNIVERSITY OF MINNESOTA

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

Budget	Year 1
Salaries and Wages	$191,859
Fringe Benefits	$57,767
Personnel Costs (Subtotal)	$249,626
Materials & Supplies	$83,016
Travel	$2,201
Other	$5,000
Subawards/Consortium/Contractual Costs	$151,102
Publication Costs	$3,500
ADP/Computer Services	$7,342
Equipment or Facility Rental/User Fees	$2,000
Tuition Remission	$16,918
TOTAL FEDERAL DC	$520,705
TOTAL FEDERAL F&A	$207,727
TOTAL COST	$728,432

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	55%
F&A Cost Base 1	$377,685
F&A Costs 1	$207,727

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:06 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI179891
Federal Award Date
04/18/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
Mireille Kamariza, PHD

kamariza@ucla.edu
510-646-5992

8. Authorized Official
Mr. Evan Garcia
egarcia@research.ucla.edu
310-794-0171

Federal Agency Information

9. Awarding Agency Contact Information
WINSTON MORGAN Downing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
winston.downing@nih.gov
(406) 363-9242

10. Program Official Contact Information
Karen A. Lacourciere
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
lacourcierek@niaid.nih.gov
240-627-3297

Federal Award Information

11. Award Number
1R01AI179891-01

12. Unique Federal Award Identification Number (FAIN)
R01AI179891

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A Rapid Phenotypic Drug Susceptibility Testing System for Tuberculosis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/23/2024 **– End Date** 06/30/2025	
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	$675,156
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$675,156
26. Project Period Start Date 08/23/2024 **– End Date** 06/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$675,156

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.

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 – 1R01AI179891-01 REVISED

Principal Investigator(s):
Mireille Kamariza, PHD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES 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 R01AI179891. 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: 4/18/2025 12:04 AM

Salaries and Wages	$150,440
Fringe Benefits	$40,918
Personnel Costs (Subtotal)	$191,358
Equipment	$25,000
Materials & Supplies	$60,015
Other	$16,187
Subawards/Consortium/Contractual Costs	$199,999
Federal Direct Costs	$492,559
Federal F&A Costs	$182,597
Approved Budget	$675,156
Total Amount of Federal Funds Authorized (Federal Share)	$675,156
TOTAL FEDERAL AWARD AMOUNT	$675,156
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$675,156	$675,156

Fiscal Information:
Payment System Identifier: 1956006143A1
Document Number: RAI179891A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
AI	8472364	$675,156

NIH Administrative Data:
PCC: M33C BR / **OC**: 41021 / **Released**: 04/17/2025
Award Processed: 04/18/2025 12:04:54 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI179891-01 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 – 1R01AI179891-01 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:04 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.

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) R01AI179891. 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: 4/18/2025 12:04 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 – AI SPECIFIC AWARD CONDITIONS – 1R01AI179891-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revised Award: It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:04 AM

UNIVERSITY OF CALIFORNIA LOS ANGELES 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.

Supersedes previous Notice of Award dated **09/14/2024**. All other terms and conditions still apply to this award.

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REVISED AWARD:

This award is revised to increase the funding level to 100% of the approved budget for the initial budget period. Out-year commitments for continuation awards remain unchanged.

Supersedes previous Notice of Award dated **08/22/2024**. All other terms and conditions still apply to this award.

*****

In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Future budget year(s) committed amounts were adjusted accordingly. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

*****

This Notice of Award (NoA) includes funds for **Central Michigan University** in the amount of **$90,000**.

This Notice of Award (NoA) includes funds for **University of the Witwatersrand (South Africa)** in the amount of **$90,000**.

*****

Research conducted at the following site(s) must be reported in the Research Performance Progress Report (RPPR), Section G.9 (Foreign component):

- **University of the Witwatersrand (South Africa)**

*****

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:04 AM

biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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.

*****

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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). 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.

SPREADSHEET SUMMARY

AWARD NUMBER: 1R01AI179891-01 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1
Salaries and Wages	$150,440
Fringe Benefits	$40,918
Personnel Costs (Subtotal)	$191,358
Equipment	$25,000
Materials & Supplies	$60,015
Other	$16,187
Subawards/Consortium/Contractual Costs	$199,999
TOTAL FEDERAL DC	$492,559
TOTAL FEDERAL F&A	$182,597
TOTAL COST	$675,156

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	57.5%
F&A Cost Base 1	$317,560
F&A Costs 1	$182,597

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:04 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI184122
Federal Award Date
04/18/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF 7 ASHINGTON
4, , , WROOBLYN AVE NE
SEATTLE37 A 98195

2. Congressional District of Recipient
06

3. Payment System Identifier (ID)
191J0015, 6A1

4. Employer Identification Number (EIN)
91J0015, 6

5. Data Universal Numbering System (DUNS)
J056994J9

6. Recipient's Unique Entity Identifier
HD17 MNJ9457 J

8. Proᵀect Director or Principal Investigator
GerK an Gustamo Gornalusse3PHD
Assistant Professor
gerK agz uk @du
20J-, 2J-9555

j . Authorized Official
Carol Rhodes

Federal Agency Information

9. Awarding Agency Contact Information
Madea c@Marini.
Contravt Grants ManageK ent Swevialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
K adea@K arini. z nih@om
, 01-6J1-J, 02

10. Program Official Contact Information
Diane M@Lak renve
PrograK Rewresentatime
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
diane@ak renve2z nih@om
240-J26-, 202

Federal Award Information

11. Award Number
1R01AI184122-01

12. Unique Federal Award Identification Number (FAIN)
R01AI184122

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Proᵀect Title
Role of intestinal K ivrofold pM(vells in vreating a hotswot enmironK ent for HIV reservoir wersistenve and reavtimation

15. Assistance Listing Number
9, @55

16. Assistance Listing Program Title
Allerg) and Infevtious Diseases Researvh

18. Award Action Type
Nek CoK weting pREVISED(

1j . Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/22/2024 **– End Date** 04/, 0/2025	
20. Total Amount of Federal Funds Obligated by this Action	y0
20 a@Direvt Cost AK ount	y0
20 b@Indirevt Cost AK ount	y0
21. Authori$ed Carr) omer	
22. Offset	
23. Total AK ount of Federal Funds Obligated this budget weriod	y8293, 9J
24. Total Approved Cost Sharing or Matching, where applicable	y0
25. Total Federal and Non-Federal Approved this Budget Period	y8293, 9J
26. Proᵀect Period Start Date 05/22/2024 **– End Date** 04/, 0/2025	
28. Total AK ount of the Federal Ak ard invluding Awwromed Cost Sharing or Matvhing this Projevt Period	y8293, 9J

2j . Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
EK il) Linde

30. Remarks

Avvewtanve of this ak ard3invluding the "TerK s and Conditions3 is av. nok ledged b) the reviwient k hen funds are drak n dok n or otherk ise requested froK the grant wa) K ent s) steK @

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RESEARCH
DewartK ent of Health and HuK an Sermives
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1R01AI1j 4122-01 REVISED

Principal Investigator(s):
GerK an Gustamo Gornalusse3PHD

Award e-mailed to: gvsfundz uk @du

Dear Authori$ed Offivial:

The National Institutes of Health hereb) remises this ak ard psee "Ak ard Calvulation" in Sevtion I and "TerK s and Conditions" in Sevtion III(to UNIVERSITY OF 7 ASHINGTON in suwwort of the abome referenved wrojevt@ This ak ard is wursuant to the authorit) of 42 USC 241 42 CFR 52 and is subjevt to the requireK ents of this statute and regulation and of other referenved3invorworated or attavhed terK s and vonditions@

Avvewtanve of this ak ard3invluding the "TerK s and Conditions3" is av. nok ledged b) the reviwient k hen funds are drak n dok n or otherk ise requested froK the grant wa) K ent s) steK @

Eavh wublivation3wress release3or other dovuK ent about researvh suwworted b) an NIH ak ard K ust invlude an av. nok ledgK ent of NIH ak ard suwwort and a disvlaiK er suvh as "Researvh reworted in this wublivation k as suwworted b) the National Institute Of Allerg) And Infevtious Diseases of the National Institutes of Health under Ak ard NuK ber R01AI184122@The vontent is solel) the reswonsibilit) of the authors and does not nevessaril) rewresent the offivial miek s of the National Institutes of Health@Prior to issuing a wress release vonverning the outvoK e of this researvh3wlease notif) the NIH ak arding IC in admanve to allok for voordination@

Ak ard reviwients K ust wroK ote objevtimit) in researvh b) establishing standards that wromide a reasonable exwevtation that the design3vonduvt and reworting of researvh funded under NIH ak ards k ill be free froK bias resulting froK an Inmestigator's Finanvial Conflivt of Interest pFCOI(3in avvordanve k ith the 2011 remised regulation at 42 CFR Part 50 Subwart F@The Institution shall subK it all FCOI reworts to the NIH through the eRA CoK K ons FCOI Module@The regulation does not awwl) to Phase I SK all Wusiness Innomatime Researvh pSWIR(and SK all Wusiness Tevhnolog) Transfer pSTTR(ak ards@Consult the NIH k ebsite httw://grants@nih@gom/grants/woliv)/voi/ for a lin. to the regulation and additional iK wortant inforK ation@

If)ou hame an) questions about this ak ard3wlease direvt questions to the Federal Agenv) vontavts@

Sinverel))ours3

EK il) Linde
Grants ManageK ent Offiver
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional inforK ation follok s

Cumulative Award Calculations for this Budget Period (U.S. Dollars)
Salaries and Wages y1623158

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:09 AM

Fringe Benefits	y413JJ5
Personnel Costs (Subtotal)	y21, 382,
Materials & Supplies	y2J3100
Travel	y180
Other	y11J3220
Subawards/Consortium/Contractual Costs	y2083J, 9
Equipment or Facility Rental/User Fees	y23000
Federal Direct Costs	y5JJ39J2
Federal F&A Costs	y2J234, 4
Approved Budget	y8293, 9J
Total Amount of Federal Funds Authorized (Federal Share)	y8293, 9J
TOTAL FEDERAL AWARD AMOUNT	y8293, 9J
AMOUNT OF THIS ACTION (FEDERAL SHARE)	y0

SUMMARY TOTALS FOR ALL YEARS pfor this DovuK ent NuK ber(		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	y8293, 9J	y8293, 9J

Fiscal Information:

Payment System Identifier:	191J0015, 6A1
Document Number:	RAI184122A
PMS Account Type:	P pSubavvount(
Fiscal Year:	2024

IC	CAN	2024
AI	8462, 00	y8293, 9J

NIH Administrative Data:
PCC: A2JD / **OC**: 41021 / **Released**: 04/16/2025
Award Processed: 04/18/2025 12:09:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI1j 4122-01 REVISED

For wa) K ent and HHS Offive of Inswevtor General Hotline inforK ation3see the NIH HoK e Page at httw://grants@ih@om/grants/woliv)/ak ardvonditions@tK

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AI1j 4122-01 REVISED

This ak ard is based on the awwlivation subK itted to3and as awwromed b)3NIH on the abome-titled wrojevt and is subjevt to the terK s and vonditions invorworated either direvtl) or b) referenve in the follok ing:

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b@ Conditions on avtimities and exwenditure of funds in other statutor) requireK ents3suvh as those invluded in awwrowriations avts@
v@ 45 CFR Part 65@
d@ National Poliv) RequireK ents and all other requireK ents desvribed in the NIH Grants Poliv) StateK ent3invluding addenda in effevt as of the beginning date of the budget weriod@
e@ Federal Ak ard PerforK anve Goals: As required b) the weriodiv rewort in the RPPR or in the final wrogress rewort k hen awwlivable@
f@ This ak ard notive3INCLUDING THE TERMS AND CONDITIONS CITED WELO7 @

pSee NIH HoK e Page at httw://grants@ih@om/grants/woliv)/ak ardvonditions@tK for vertain referenves vited abome(@

Research and Development (R&D): All ak ards issued b) the National Institutes of Health pNIH(K eet the definition of "Researvh and DemelowK ent" at 45 CFR Part§ 65@. As suvh3auditees should identif) NIH ak ards as wart of the R&D vluster on the Svhedule of Exwenditures of Federal Ak ards pSEFA(@The auditor should test NIH ak ards for voK wlianve as instruvted in Part V3Clusters of PrograK s@NIH revogni$es that soK e ak ards K a) hame another vlassifivation for wurwoses of indirevt vosts@The auditor is not required to

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rewort the disvonnevt pi@@the ak ard is vlassified as R&D for Federal Audit RequireK ent wurwoses but non-researvh for indirevt vost rate wurwoses(3unless the auditee is vharging indirevt vosts at a rate other than the rateps(swevified in the ak ard dovuK entps(@

This institution is a signator) to the Federal DeK onstration PartnershiwpFDP(Phase VII AgreeK ent k hivh requires avtime institutional wartiviwation in nek or ongoing FDP deK onstrations and wilots@

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This ak ard is subjevt to the requireK ents of 2 CFR Part 25 for institutions to obtain a unique entit) identifier pUEI(and K aintain an avtime registration in the S) steK for Ak ard ManageK ent pSAM(@Should a vonsortiuK /subak ard be issued under this ak ard3a UEI requireK ent K ust be invluded@See httw://grants@ih@om/grants/woliv)/ak ardvonditions@htK for the full NIH ak ard terK iK wleK enting this requireK ent and other additional inforK ation@

This ak ard has been assigned the Federal Ak ard Identifivation NuK ber pFAIN(R01AI184122@Reviwients K ust dovuK ent the assigned FAIN on eavh vonsortiuK /subak ard issued under this ak ard@

Wased on the wrojevt weriod start date of this wrojevt3this ak ard is li. el) subjevt to the Transwarenv) Avt subak ard and exevutime voK wensation reworting requireK ent of 2 CFR Part 160@There are vonditions that K a) exvlude this ak ard; see httw://grants@ih@om/grants/woliv)/ak ardvonditions@htK for additional ak ard awwlivabilit) inforK ation@

In avvordanve k ith P@@110-1J13voK wlianve k ith the NIH Publiv Avvess Poliv) is nok K andator)@For K ore inforK ation3see NOT-OD-08-0, , and the Publiv Avvess k ebsite: httw://wublivavvess@ih@om/@

This ak ard rewresents the final)ear of the voK wetitime segK ent for this grant@See the NIH Grants Poliv) StateK ent Sevtion 8@1 Closeout for voK wlete vloseout requireK ents at: httw://grants@ih@om/grants/woliv)/woliv)@htK #gws@

A final exwenditure Federal Finanvial Rewort pFFR(pSF 425(K ust be subK itted through the Pa) K ent ManageK ent S) steK pPMS(k ithin 120 da) s of the weriod of werforK anve end date; see the NIH Grants Poliv) StateK ent Sevtion 8@2@1 Finanvial Reworts3httw://grants@ih@om/grants/woliv)/woliv)@htK #gws3for additional inforK ation on this subK ission requireK ent@The final FFR K ust indivate the exavt balanve of unobligated funds and K a) not reflevt an) unliquidated obligations@There K ust be no disvrewanvies betk een the final FFR exwenditure data and the real-tiK e vash drak dok n data in PMS@NIH k ill vlose the ak ards using the last revorded vash drak dok n lemel in PMS for ak ards that do not require a final FFR on exwenditures@It is iK wortant to note that for finanvial vloseout3if a grantee fails to subK it a required final exwenditure FFR3NIH k ill vlose the grant using the last revorded vash drak dok n lemel@

A Final Inmention StateK ent and Certifivation forK pHHS 5J8(3pnot awwlivable to training3vonstruvtion3 vonferenve or vanver eduvation grants(K ust be subK itted k ithin 120 da) s of the exwiration date@The HHS 5J8 forK K a) be dok nloaded at: httw://grants@ih@om/grants/forK s@htK @This waragrawh does not awwl) to Training grants3Fellok shiws3and vertain other wrograK s—i@@avtimit) vodes C0J3D423D4, 3D613DP63G063 G083G113B123B1J3B, 03P093P403P413P513R1, 3R253R283R, 03R903RL53RL93S103S143S153U1, 3U143U413 U423U453UCJ3UC63UR23X013X02@

Unless an awwlivation for voK wetitime renek al is subK itted3a Final Researvh PerforK anve Progress Rewort pFinal RPPR(K ust also be subK itted k ithin 120 da) s of the weriod of werforK anve end date@If a voK wetitime renek al awwlivation is subK itted wrior to that date3then an InteriK RPPR K ust be subK itted b) that date as k ell@Instruvtions for wrewaring an InteriK or Final RPPR are at: httws://grants@ih@om/grants/rwwr/rwwr_instruvtion_guide@df@An) other swevifiv requireK ents set forth in the terK s and vonditions of the ak ard K ust also be addressed in the InteriK 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 elevtroniv subK ission of the final inmention stateK ent through the Closeout feature in the CoK K ons@

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:09 AM

NOTE: If this is the final) ear of a voK wetitime segK ent due to the transfer of the grant to another institution3 then a Final RPPR is not required@Hok emer3a final exwenditure FFR is required and K ust be subK itted elevtronivall) as noted abome@If not alread) subK itted3the Final Inmention StateK ent is required and should be sent direvtl) to the assigned Grants ManageK ent Swevialist@

Reviwients K ust adK inister the wrojevt in voK wlianve k ith federal vimil rights lak s that wrohibit disvriK ination on the basis of rave3volor3national origin3disabilit) 3age3and voK wl) k ith awwlivable vonsvienve wrotevtions@The reviwient k ill voK wl) k ith awwlivable lak s that wrohibit disvriK ination on the basis of sex3k hivh invludes disvriK ination on the basis of gender identit) 3sexual orientation3and wregnanv) @CoK wlianve k ith these lak s requires ta. ing reasonable stews to wromide K eaningful avvess to wersons k ith liK ited English wrofivienv) and wromiding wrograK s that are avvessible to and usable b) wersons k ith disabilities@The HHS Offive for Cimil Rights wromides guidanve on voK wl) ing k ith vimil rights lak s enforved b) HHS@See https://k k k (@hhs@om/vimil-rights/for-wromiders/wromider-obligations/index(@htK l and https://k k k (@hhs@om/@

- Reviwients of FFA K ust ensure that their wrograK s are avvessible to wersons k ith liK ited English wrofivienv) @For guidanve on K eeting the legal obligation to ta. e reasonable stews to ensure K eaningful avvess to wrograK s or avtimities b) liK ited English wrofivient indimiduals3 see https://k k k (@hhs@om/vimil-rights/for-indimiduals/swevial-towivs/liK ited-english-wrofivienv) /favt-sheet-guidanve/index(@htK l and https://k k k (@ew@om@
- For inforK ation on an institution's swevifiv legal obligations for serming qualified indimiduals k ith disabilities3invluding wromiding wrograK avvess3reasonable K odifivations3and to wromide effevtime voK K univation3see https://k k k (@hhs@om/ovr/vimilrights/understanding/disabilit) /index(@htK l@
- HHS funded health and eduvation wrograK s K ust be adK inistered in an enmironK ent free of sexual harassK ent; see https://k k k (@hhs@om/vimil-rights/for-indimiduals/sex-disvriK ination/index(@htK l@ For inforK ation about NIH's voK K itK ent to suwworting a safe and reswevtful k or. enmironK ent3 k ho to vontavt k ith questions or vonverns3and k hat NIH's exwevtations are for institutions and the indimiduals suwworted on NIH-funded ak ards3wlease see https://grants@ih@om/grants/woliv) /harassK ent(@htK @
- For guidanve on adK inistering wrograK s in voK wlianve k ith awwlivable federal religious nondisvriK ination lak s and awwlivable federal vonsvienve wrotevtion and assoviated anti-disvriK ination lak s3see https://k k k (@hhs@om/vonsvienve/vonsvienve-wrotevtions/index(@htK l and https://k k k (@hhs@om/vonsvienve/religious-freedoK /index(@htK l@

In avvordanve k ith the regulator) requireK ents wromided at 45 CFR 65@1, and Awwendix XII to 45 CFR Part 653reviwients that hame vurrentl) avtime Federal grants3vooweratime agreeK ents3and wrovureK ent vontravts k ith vuK ulatime total malue greater than y103 0003 000 K ust rewort and K aintain inforK ation in the S) steK for Ak ard ManageK ent pSAM(about vimil3vriK inal3and adK inistratime wroveedings in vonnevtion k ith the ak ard or werforK anve of a Federal ak ard that reavhed final diswosition k ithin the K ost revent fime-) ear weriod@The reviwient K ust also K a. e seK iannual disvlosures regarding suvh wroveedings@Proveedings inforK ation k ill be K ade wublivl) amailable in the designated integrit) and werforK anve s) steK pvurrentl) the Federal Ak ardee PerforK anve and Integrit) InforK ation S) steK pFAPIIS((@Full reworting requireK ents and wrovedures are found in Awwendix XII to 45 CFR Part 65@This terK does not awwl) to NIH fellok shiws@

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R01AI1j 4122-01 REVISED

Clinival Trial Indivator: No
This ak ard does not suwwort an) NIH-defined Clinival Trials@See the NIH Grants Poliv) StateK ent Sevtion 1@2 for NIH definition of Clinival Trial@

Revised Award: It is the woliv) of NIH not to wrioriti$e researvh wrograK s related to DEI: Researvh wrograK s based wriK aril) on artifivial and non-svientifiv vategories3invluding aK orwhous equit) objevtimes3are antithetival to the svientifiv inquir) 3do nothing to exwand our . nok ledge of liming s) steK s3wromide lok returns on inmestK ent3and ultiK atel) do not enhanve health3lengthen life3or reduve illness@7 orse3so-valled dimersit) 3equit) 3and invlusion p"DEI"(studies are often used to suwwort unlak ful disvriK ination on the basis of rave and other wrotevted vharavteristivs3k hivh harK s the health of AK erivans@Therefore3it is the woliv) of NIH not to wrioriti$e suvh researvh wrograK s@Therefore3no additional funding k ill be ak arded for this

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:09 AM

wrojevt3and all future) ears hame been reK omed@

UNIVERSITY OF 7 ASHINGTON K a) request funds to suwwort watient safet) and orderl) vloseout of the wrojevt3and reK aining funds k ill be deobligated@Funds used to suwwort an) other researvh avtimities k ill be disallok ed and revomered@Please be admised that) our organi$ation3as wart of the orderl) vloseout wrovess k ill need to subK it the nevessar) vloseout dovuK ents pi@@Final Researvh PerforK anve Progress Rewort3 Final Inmention StateK ent3and the Final Federal Finanvial Rewort pFFR(3as awwlivable(k ithin 120 da) s of the end of this grant@

NIH is ta. ing this enforveK ent avtion in avvordanve k ith 2 C@R@@ 200@40 as iK wleK ented in NIH GPS Sevtion 8@2@@This remised ak ard rewresents the final devision of the NIH@t shall be the final devision of the DewartK ent of Health and HuK an Sermives pHHS(unless k ithin , 0 da) s after reveiming this devision) ou K ail or eK ail a k ritten notive of awweal to Dr@Matthek MeK oli@Please invlude a vow) of this devision3) our awweal justifivation3total aK ount in diswute3and an) K aterial or dovuK entation that k ill suwwort) our wosition@Finall) 3the awweal K ust be signed b) the institutional offivial authori$ed to sign ak ard awwlivations and K ust be dated no later than , 0 da) s after the date of this notive@

Suwersedes wremious Notive of Ak ard dated 05/22/2024@All other terK s and vonditions still awwl) to this ak ard@

+++++

REMINDER: This grant is funded for HIV/AIDS researvh@Per the NIH Remitali$ation Avt of 199, 3funds are restrivted for HIV/AIDS researvh and vannot be re-budgeted for other wurwoses@

%%%%%%%%%

The budget period anniversary start date for future year(s) will be **May 1.**

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In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Future budget year(s) committed amounts were adjusted accordingly. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

****

This ak ard invludes huK an subjevt researvh studies and K ust vonforK to the DHHS wolivies for the Protevtion of HuK an Subjevts researvh3k hivh are a terK and vondition of ak ard@HuK an subjevts researvh is vomered b) the 2018 CoK K on Rule3and K a) not be initiated until the assoviated wrotovols hame reveimed IRWawwromal as swevified in 45 CFR 4J@Failure to voK wl) k ith the terK s and vonditions of ak ard K a) result in the disallok anve of vosts and/or additional enforveK ent avtions as outlined in Sevtion 8@ of the NIH Grants Poliv) StateK ent@

%%%%%%%%%

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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). 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 ManageK ent and Sharing Poliv) : Awwlivable

This wrojevt is exwevted to generate svientifiv data@Therefore3the Final NIH Poliv) for Data ManageK ent and Sharing awwlies@The awwromed Data ManageK ent and Sharing pDMS(Plan is hereb) invorworated as a terK and vondition of ak ard3and the reviwient shall K anage and disseK inate svientifiv data in avvordanve k ith the awwromed wlan@An) signifivant vhanges to the DMS Plan pe@@mek svientifiv direvtion3a different data rewositor) 3or a tiK eline remission(require NIH wrior awwromal@Failure to voK wl) k ith the awwromed DMS wlan K a) result in suswension and/or terK ination of this ak ard3k ithholding of suwwort3audit disallok anves3 and/or other awwrowriate avtion@See NIH Grants Poliv) StateK ent Sevtion 8@@ for K ore inforK ation on data K anageK ent and sharing exwevtations@

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:09 AM

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AI184122-01 REVISED

INSTITUTION: UNIVERSITY OF 7 ASHINGTON

W.udget	Year 1
Salaries and 7 ages	y1623158
Fringe Wenefits	y413JJ5
Personnel Costs pSubtotal(	y21, 382,
Materials & Suwwlies	y2J3100
Tranel	y180
Other	y11J3220
Subak ards/ConsortiuK /Contravtual Costs	y2083J, 9
EquiwK ent or Favilit) Rental/User Fees	y23000
TOTAL FEDERAL DC	y5JJ39J2
TOTAL FEDERAL F&A	y2J234, 4
TOTAL COST	y8293, 9J

Favilities and AdK inistratine Costs	Year 1
F&A Cost Rate 1	55@5*
F&A Cost Wase 1	y14J3505
F&A Costs 1	y813421
F&A Cost Rate 2	6J@5*
F&A Cost Wase 2	y2, J3J18
F&A Costs 2	y1813301,

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/18/2025 12:09 AM

National Institutes of Health
Office of Extramural Research

March 20, 2025

Bethany Jenkins
University of Rhode Island
bdjenkins@uri.edu

Dear Bethany Jenkins:

Effective with the date of this letter, funding for Project Number 1R01 DA058994-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 15, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Pamela Fleming, Chief Grants Management Officer, National Institute on Drug Abuse
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: thomas.mann@research.ucla.edu
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/24/2025

Mann, Thomas
University Of California Los Angeles
thomas.mann@research.ucla.edu

Dear Mann, Thomas:

Effective with the date of this letter, funding for Project Number 1R01DK132735-01 is hereby terminated pursuant to the Fiscal Year 2021 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 2021 Policy Statement applies to your project because NIH approved your grant on 9/17/2021, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2021 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 Dee Doherty, Chief Grants Management Officer, NIDDK
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# R01DK132735
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
Arjun Deb, MD (Contact)
Associate Professor
adeb@mednet.ucla.edu
310-825-9871

8. Authorized Official
Thomas Mann

Federal Agency Information

9. Awarding Agency Contact Information
Gishell Cruz
Extramural Support Assistant
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
cruzgv@mail.nih.gov

10. Program Official Contact Information
RAJATAVA Basu

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
raj.basu@nih.gov
240-255-0845

Federal Award Information

11. Award Number
1R01DK132735-01

12. Unique Federal Award Identification Number (FAIN)
R01DK132735

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Metabolic and epigenetic reprogramming of vital organs in SARS-CoV-2 induced systemic toxicity

15. Assistance Listing Number
93.310

16. Assistance Listing Program Title
Trans-NIH Research Support

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/17/2021 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$3,636,473
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$3,636,473
26. Project Period Start Date 09/17/2021 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$6,015,134

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Dee Doherty

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 12:00 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 1R01DK132735-01 REVISED

Principal Investigator(s):
Vaithilingaraja Arumugaswami
Arjun Deb (contact), MD
THOMAS G GRAEBER, PHD
Matteo Pellegrini, PHD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES 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 Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number R01DK132735. 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,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$1,221,884
Fringe Benefits	$440,331
Personnel Costs (Subtotal)	$1,662,215
Materials & Supplies	$563,315
Other	$96,801
Publication Costs	$8,742
Federal Direct Costs	$2,331,073
Federal F&A Costs	$1,305,400
Approved Budget	$3,636,473
Total Amount of Federal Funds Authorized (Federal Share)	$3,636,473
TOTAL FEDERAL AWARD AMOUNT	$3,636,473
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (1) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
1R01DK132735-01	$3,636,473
3R01DK132735-01S1	$2,378,661
TOTAL	**$6,015,134**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$3,636,473	$6,015,134

Fiscal Information:
Payment System Identifier: 1956006143A1
Document Number: RDK132735AC3
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021
OD	8045357	$3,636,473

NIH Administrative Data:
PCC: DRB INFL / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:00:44 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01DK132735-01 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 – 1R01DK132735-01 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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01DK132735. 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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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:

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

Additional Costs

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 1R01DK132735-01 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 #4 Termination of Award

It is the policy of NIH not to prioritize the amelioration of the effects of the pandameic. Therefore, this project is terminated. University of California Los Angeles 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.

REVISION #3 : No-Cost Extension
The purpose of this revision is to extend the final budget/project period without additional funds in accordance with the recipient's request dated 8/26/24. The recipient is responsible for ensuring that all necessary human/animal assurances are valid during this extension period.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ALSO APPLY TO THIS AWARD:

Revision #2

This award is revised to add the following term:

This award provides funds of $ **$3,636,473** Total Costs ($2,331,073 Direct Costs and $ 1,305,400 F&A Costs) to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds provide support for the period 9/17/2021-8/31/2024. These funds are restricted the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIDDK prior approval

The following terms from the previous notice of award also apply to this award:

Revision #1

This revised award reflects NIDDK's acceptance of the certification of Institutional Animal Care and Use Committee approval and removes the restrictive term on the Notice of Award.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

The following terms from the previous notice of award also apply to this award:

This award is supported by the NIH Common Fund, through the Office of Strategic Coordination/Office of the NIH Director. Publications derived from this research should acknowledge support by the NIH Common Fund with reference to the specific grant number 1 R01 DK 132735 - 01. These funds are restricted for use in this project only.

This award has been divided into 2 phases; Phase I consist of years 1-3 and Phase II will consist of year 4-5. The Phase II continuation application package is due 2 months prior to the anticipated start date of Phase II, which is **9/1/2024**. It should be submitted electronically as a complete PDF file to the assigned Program Officer and Grants Management Specialist listed on the Notice of Award.

For Phase I, you will receive the funding for all 3 years up front. Years 4 & 5 will be funded seperately. A progress report is due annually on or before the anniversary of the budget start date, i.e., September 1, 2022, September 1, 2023, September 1, 2024. The report must be submitted using the Research Performance Progress Report (RPPR).

Award Budget
The award is based on the IRG recommendations as noted on the Summary Statement and no further administrative reductions have been taken.

See the budget information below for additional information.

Model Organism Sharing Plan
The grantee is required to follow the model organism sharing plan included in the application and may not implement any changes in the plan without the written prior approval of the NIDDK.

Prior Approvals with Multiple PI's
In keeping with NOT-OD-11-118, as this grant has multiple Principal Investigators (Dr. Arjun Deb, Dr. Thomas Graeber,Dr. Vaithi Arumugaswamy and Dr. Matteo Pellegrini), 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

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01DK132735-01 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1
Salaries and Wages	$1,221,884
Fringe Benefits	$440,331
Personnel Costs (Subtotal)	$1,662,215
Materials & Supplies	$563,315
Other	$96,801
Publication Costs	$8,742
TOTAL FEDERAL DC	$2,331,073
TOTAL FEDERAL F&A	$1,305,400
TOTAL COST	$3,636,473

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	56%
F&A Cost Base 1	$2,331,072
F&A Costs 1	$1,305,400

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:00 AM

From: Bulls, Michelle G. (NIH/OD) [E]
To: sharon.louie@ucsf.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Sharon Louie
University Of California, San Francisco
sharon.louie@ucsf.edu

Dear Sharon Louie:

Effective with the date of this letter, funding for Project Number 1R01HD112464-01A1 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 9/21/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10]

See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

From: Bulls, Michelle G. (NIH/OD) [E]
To: clam13@uci.edu
Subject: Grant Termination Notification
Date: Tuesday, April 1, 2025 9:23:00 AM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/1/2025

Lam, Cindy
University Of California-Irvine
clam13@uci.edu

Dear Lam, Cindy:

Effective with the date of this letter, funding for Project Number 1R01MD019765-01 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 9/20/2024, 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: uw-aor@u.washington.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Rhodes, Carol
University Of Washington
uw-aor@u.washington.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 1R01TW012904-01 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 8/9/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Bruce Butrum, Chief Grants Management Officer, FIC
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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: gcat3@yale.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Ms. Varick, Tina
Yale University
gcat3@yale.edu

Dear Ms. Varick, Tina:

Effective with the date of this letter, funding for Project Number 1R21HD110617-01A1 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 9/7/2023, 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."

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)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

March 10, 2025

Heather Clark,
Arizona State University
660 S. Mill Avenue Ste. 204
Tempe, AZ 85281

Ms. Clark,

Funding for Project Number 1R21HD110837-01A1 is hereby terminated pursuant to the 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 08/23/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 1R21HD110837-01A1 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

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,

Lauren Ruane
Deputy Branch Chief
Grants Management Branch
Eunice Kennedy Shriver National Institute of Child Health and Human Development

[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).

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Militano, Jeni (NIH/NIA/ERP) [E]
Subject: FW: Grant Termination Notification
Date: Friday, March 21, 2025 1:55:18 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 12:28 PM
To: maggie.cho@ucsf.edu
Subject: Grant Termination Notification

National Institutes of Health
Office of Extramural Research

3/21/2025

Cho, Magdalene
University Of California, San Francisco
maggie.cho@ucsf.edu

Dear Cho, Magdalene:

Effective with the date of this letter, funding for Project Number 1R56AG079510-01A1 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 9/21/2023, 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."

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 Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4]

NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

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.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

From: Bulls, Michelle G. (NIH/OD) [E]
To: rhgelma@emory.edu
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/24/2025

Rachel Gelman
Emory University
rhgelma@emory.edu

Dear Rachel Gelman:

Effective with the date of this letter, funding for Project Number 1U19AI171403-01 is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 5/16/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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)

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:34 AM
To: Schechter, Shannon <Shannon.Schechter@ucsf.edu>
Subject: Grant Termination Notification

This Message Is From an External Sender

This message came from outside your organization.

National Institutes of Health
Office of Extramural Research

3/21/2025

Shannon P Schechter
University Of California, San Francisco
Shannon.Schechter@ucsf.edu

Dear Shannon P Schechter:

Effective with the date of this letter, funding for Project Number 5F31AA030722-02 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

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

[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)

From: Inge Siggelkow
To: Inge Siggelkow
Subject: FW: Grant Termination Notification
Date: Friday, April 11, 2025 4:18:24 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 12:35 PM
To: Patricia Hokanson <PHokanson@PIRE.org>
Subject: Grant Termination Notification

This is an External Email. Please be cautious when opening attachments and/or clicking links.

3/21/2025

Patricia Susan Hokanson
Pacific Institute For Res And Evaluation
phokanson@pire.org

Dear Patricia Susan Hokanson:

Effective with the date of this letter, funding for Project Number 5R01NR021019-03 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 2/1/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Brian Albertini, Chief Grants Management Officer, NINR
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)

Case: 25-1611 Document: 00118350955 Page: 179 Date Filed: 10/09/2025 Entry ID: 6756750

Benjamin Wichterman <bwichter@umn.edu>

Fwd: Grant Termination Notification

Patrick Donnell <donne096@umn.edu>
To: Benjamin Wichterman <bwichter@umn.edu>

Fri, Mar 21, 2025 at 12:15 PM

FYI....CON 96568 for Dr. Rosser.

Please immediately notify the PI, department and any subrecipients.

Thank you

---------- Forwarded message ---------
From: **Bulls, Michelle G. (NIH/OD) [E]** <michelle.bulls@nih.gov>
Date: Fri, Mar 21, 2025 at 11:37 AM
Subject: Grant Termination Notification
To: donne096@umn.edu <donne096@umn.edu>

3/21/2025

Patrick Donnell

University Of Minnesota

donne096@umn.edu

Dear Patrick Donnell:

Effective with the date of this letter, funding for Project Number 3R01AG075734-03S1 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 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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,

Case: 25-1611 Document: 00118350955 Page: 173 Date Filed: 10/09/2025 Entry ID: 6756750

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jeni Militano (Acting), Chief Grants Management Officer, NIA

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

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Patrick Donnell
Principal Grants and Contracts Officer
Office of Sponsored Projects Administration
University of Minnesota
450 McNamara Alumni Center
200 Oak Street SE
Minneapolis, MN 55455-2070
(612) 301-1411
donne096@umn.edu

Upcoming out of office: March 27th-April 4th

National Institutes of Health
Office of Extramural Research

March 21, 2025

Montel Rudolph
Charles R. Drew University of Medicine and Science
montelrudoph@cdrewu.edu

Dear Montel Rudolph:

Effective with the date of this letter, funding for Project Number 2U54 MD007598-16 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 23, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: aor@hawaii.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Ms. Naomi Chow
University Of Hawaii At Manoa
aor@hawaii.edu

Dear Ms. Naomi Chow:

Effective with the date of this letter, funding for Project Number 3U54MD007601-38S2 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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: clam13@uci.edu
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/24/2025

Cindy Lam
University Of California-Irvine
clam13@uci.edu

Dear Cindy Lam:

Effective with the date of this letter, funding for Project Number 4R01AI158060-05 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 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."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations

imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.* [8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI158060
Federal Award Date
04/07/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA IRVINE
160 ALDRICH HALL
IRVINE, CA 92697

2. Congressional District of Recipient
47

3. Payment System Identifier (ID)
1952226406A1

4. Employer Identification Number (EIN)
952226406

5. Data Universal Numbering System (DUNS)
046705849

6. Recipient's Unique Entity Identifier
MJC5FCYQTPE6

7. Project Director or Principal Investigator
Lbachir BenMohamed, PHD
Professor And Director
Lbenmoha@uci.edu
949-824-8937

8. Authorized Official
Cindy Lam
clam13@uci.edu
949-824-2918

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
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
4R01AI158060-05

12. Unique Federal Award Identification Number (FAIN)
R01AI158060

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Developing a Multi-epitope Pan-Coronavirus Vaccine

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Extension with or without funds (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	$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	$727,670
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$727,670
26. Project Period Start Date 08/07/2020 **– End Date** 07/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$727,670

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: 4/8/2025 12:15 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 – 4R01AI158060-05 REVISED

Principal Investigator(s):
Lbachir BenMohamed, PHD

Award e-mailed to: awards@research.uci.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA-IRVINE 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 R01AI158060. 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: 4/8/2025 12:15 AM

Salaries and Wages	$278,305
Fringe Benefits	$89,688
Personnel Costs (Subtotal)	$367,993
Materials & Supplies	$36,500
Travel	$3,500
Other	$53,491
Publication Costs	$2,000
Federal Direct Costs	$463,484
Federal F&A Costs	$264,186
Approved Budget	$727,670
Total Amount of Federal Funds Authorized (Federal Share)	$727,670
TOTAL FEDERAL AWARD AMOUNT	$727,670
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMAR/ TOTALS FOR ALL / EARS (for this Document Number)		
/ R	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$727,670	$727,670

Fiscal Information:
Payment System Identifier: 1952226406A1
Document Number: RAI158060BC3
PMS Account Type: P (Subaccount)
Fiscal / ear: 2024

IC	CAN	2024
AI	8056063	$727,670

NIH Administrative Data:
PCC: M51Q S / **OC**: 41025 / **Released**: 04/07/2025
Award Processed: 04/08/2025 12:15:36 AM

SECTION II – PA/ MENTY HOTLINE INFORMATION – 4R01AI158060-05 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 – 4R01AI158060-05 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: 4/8/2025 12:15 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) R01AI158060. 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: 4/8/2025 12:15 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 – AI SPECIFIC AWARD CONDITIONS – 4R01AI158060-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revised Award: In compliance with the Temporary Restraining Order issued on April 3, 2025, in the United States District Court for the District of Rhode Island, Notices of Award (NOAs) issued on or after March 24, 2025, that instructed termination of certain COVID-19 funding and ceasing of activities under this award for reasons related to the end of the COVID-19 pandemic are officially **rescinded**. Activities and funding under this award are no longer terminated through April 17, 2025, or the Court rules on the Plaintiffs' motion for a preliminary injunction whichever comes first. Accordingly, award

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/8/2025 12:15 AM

activities may continue consistent with the existing terms and conditions of the award, including applicable regulations.

Therefore, effective with the date of this revised Notice of Award, funding for Project Number 4R01AI158060-05 is hereby fully reinstated; therefore, the termination letter dated 03/24/2025 is rescinded. Funds made available to UNIVERSITY OF CALIFORNIA, IRVINE used to support "Developing a Multi-epitope Pan-Coronavirus Vaccine" are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03Y26Y2025.** All other terms and conditions still apply to this award.
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THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

This award provides funds of **$727,670** Total Costs (**$463,484 Direct Cost**s and **$264,186** F&A Costs) to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds provide support for the period 08/01/2024 - 07/31/2025. These funds are restricted to prevent, prepare for, and respond to coronavirus domestically or internationally only as described in the application submitted on **05Y22Y2020** and subsequent documentation submitted **06Y14Y2024,** and may not be rebudgeted or used for any other purpose without NIAID prior approval.

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This Notice of Award (NoA) includes funds for **Sunomix Therapeutics.**

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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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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Recipients conducting research involving Select Agents (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/) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, recipients must notify the NIAID and must request and receive approval from CDC or APHIS.

Be advised that the recipient is responsible for having its subrecipients comply with the requirements pertaining to the use of Select Agents and/or Highly Pathogenic Agents.

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Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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 SUMMAR/
AWARD NUMBER: 4R01AI158060-05 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA-IRVINE

Budget	Year 5
Salaries and Wages	$278,305
Fringe Benefits	$89,688
Personnel Costs (Subtotal)	$367,993
Materials & Supplies	$36,500
Travel	$3,500
Other	$53,491
Publication Costs	$2,000
TOTAL FEDERAL DC	$463,484
TOTAL FEDERAL F&A	$264,186

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/8/2025 12:15 AM

TOTAL COST	$727,670

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	57%
F&A Cost Base 1	$463,484
F&A Costs 1	$264,186

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/8/2025 12:15 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI158060
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA IRVINE
160 ALDRICH HALL
IRVINE, CA 92697

2. Congressional District of Recipient
47

3. Payment System Identifier (ID)
1952226406A1

4. Employer Identification Number (EIN)
952226406

5. Data Universal Numbering System (DUNS)
046705849

6. Recipient's Unique Entity Identifier
MJC5FCYQTPE6

7. Project Director or Principal Investigator
Lbachir BenMohamed, PHD
Professor And Director
Lbenmoha@uci.edu
949-824-8937

8. Authorized Official
Cindy Lam
clam13@uci.edu
949-824-2918

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
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
4R01AI158060-05

12. Unique Federal Award Identification Number (FAIN)
R01AI158060

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Developing a Multi-epitope Pan-Coronavirus Vaccine

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Extension with or without funds (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2024 **– 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	$727,670
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$727,670
26. Project Period Start Date 08/07/2020 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$727,670

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 12:16 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 – 4R01AI158060-05 REVISED

Principal Investigator(s):
Lbachir BenMohamed, PHD

Award e-mailed to: awards@research.uci.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA-IRVINE 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 R01AI158060. 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 12:16 AM

Salaries and Wages	$278,305
Fringe Benefits	$89,688
Personnel Costs (Subtotal)	$367,993
Materials & Supplies	$36,500
Travel	$3,500
Other	$53,491
Publication Costs	$2,000
Federal Direct Costs	$463,484
Federal F&A Costs	$264,186
Approved Budget	$727,670
Total Amount of Federal Funds Authorized (Federal Share)	$727,670
TOTAL FEDERAL AWARD AMOUNT	$727,670
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMAR/ TOTALS FOR ALL / EARS (for this Document Number)		
/ R	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$727,670	$727,670

Fiscal Information:
Payment System Identifier: 1952226406A1
Document Number: RAI158060BC3
PMS Account Type: P (Subaccount)
Fiscal / ear: 2024

IC	CAN	2024
AI	8056063	$727,670

NIH Administrative Data:
PCC: M51Q S / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:16:56 AM

SECTION II – PA/ MENTY HOTLINE INFORMATION – 4R01AI158060-05 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 – 4R01AI158060-05 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: 3/26/2025 12:16 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) R01AI158060. 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.

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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: 3/26/2025 12:16 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 – AI SPECIFIC AWARD CONDITIONS – 4R01AI158060-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revised Award: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention 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 12:16 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 **09Y05Y2024** All other terms and conditions still apply to this award.

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THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

This award provides funds of **$727,670** Total Costs (**$463,484 Direct Cost**s and **$264,186** F&A Costs) to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds provide support for the period 08/01/2024 - 07/31/2025. These funds are restricted to prevent, prepare for, and respond to coronavirus domestically or internationally only as described in the application submitted on **05Y22Y2020** and subsequent documentation submitted **06Y14Y2024,** and may not be rebudgeted or used for any other purpose without NIAID prior approval.

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This Notice of Award (NoA) includes funds for **Sunomix Therapeutics.**

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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 support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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Recipients conducting research involving Select Agents (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/) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, recipients must notify the NIAID and must request and receive approval from CDC or APHIS.

Be advised that the recipient is responsible for having its subrecipients comply with the requirements pertaining to the use of Select Agents and/or Highly Pathogenic Agents.

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Highly Pathogenic Agents:

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:16 AM

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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 SUMMAR/
AWARD NUMBER: 4R01AI158060-05 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA-IRVINE

Budget	Year 5
Salaries and Wages	$278,305
Fringe Benefits	$89,688
Personnel Costs (Subtotal)	$367,993
Materials & Supplies	$36,500
Travel	$3,500
Other	$53,491
Publication Costs	$2,000
TOTAL FEDERAL DC	$463,484
TOTAL FEDERAL F&A	$264,186
TOTAL COST	$727,670

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:16 AM

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	57%
F&A Cost Base 1	$463,484
F&A Costs 1	$264,186

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:16 AM

National Institutes of Health
Office of Extramural Research

3/21/2025

Gregory J Sorensen
University Of Maryland Baltimore
gsore001@umaryland.edu;

Dear Gregory J Sorensen:

Effective with the date of this letter, funding for Project Number 5D43TW012274-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 7/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *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 Bruce Butrum, Chief Grants Management Officer, FIC

[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

National Institutes of Health
Office of Extramural Research

3/21/2025

Gregory J Sorensen
University Of Maryland Baltimore
gsore001@umaryland.edu;

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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.

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Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Bruce Butrum, Chief Grants Management Officer, FIC

[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# F31AI162230
Federal Award Date
04/21/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF MINNESOTA
2221 UNIVERSITY AVE SE STE 100
MINNEAPOLIS, MN 55414

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1416007513A5

4. Employer Identification Number (EIN)
416007513

5. Data Universal Numbering System (DUNS)
555917996

6. Recipient's Unique Entity Identifier
KABJZBBJ4B54

8. Project Director or Principal Investigator
Elizabeth Okafor, AB

okafo039@umn.edu
816-699-8201

j . Authorized Official
Tracy C Burdett
BURDE047@UMN.EDU
606-308-2115

Federal Agency Information

9. Awarding Agency Contact Information
Sufiyan Saeed
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
sufiyan.saeed@nih.gov
240-627-3761

10. Program Official Contact Information
Karobi Moitra
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
karobi.moitra@nih.gov
(301) 480-6893

Federal Award Information

11. Award Number
5F31AI162230-03

12. Unique Federal Award Identification Number (FAIN)
F31AI162230

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
NK Cell Cytotoxicity Against Cryptococcus neoformans in Persons with Advanced HIV and Cryptococcal Meningitis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

18. Award Action Type
Non-Competing Continuation (REVISED)

1j . Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2024 **– End Date** 01/31/2025	
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	$51,974
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$51,974
26. Project Period Start Date 02/01/2022 **– End Date** 01/31/2025	
28. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$136,511

2j . Authorized Treatment of Program Income

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: 4/21/2025 12:01 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5F31AI162230-03 REVISED

Principal Investigator(s):
Elizabeth Okafor, AB

Award e-mailed to: awards@umn.edu

Fellow's e-mail:
Elizabeth Okafor okafo039@umn.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MINNESOTA 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 Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number F31AI162230. 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)

Institutional Allowance	$4,750
Other	$16,000
Childcare Costs	$3,000

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/21/2025 12:01 AM

Stipends	$28,224
Federal Direct Costs	$51,974
Total Award	$51,974
Total Amount of Federal Funds Authorized (Federal Share)	$51,974
TOTAL FEDERAL AWARD AMOUNT	$51,974
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMAR/ TOTALS FOR ALL / EARS (for this Document Number)		
/ R	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$51,974	$51,974

Fiscal Information:

Payment System Identifier:	1416007513A5
Document Number:	FAI162230A
PMS Account Type:	P (Subaccount)
Fiscal / ear:	2024

IC	CAN	2024
AI	8012197	$48,974
AI	8012198	$3,000

NIH Administrative Data:
PCC: X79 A / **OC:** 41013 / **Released:** 2025-04-18
Award Processed: 04/21/2025 00:01:20 AM

SECTION II – PA/ MENTY HOTLINE INFORMATION – 5F31AI162230-03 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 – 5F31AI162230-03 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 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) F31AI162230. 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.

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.

National Institute Of Allergy And Infectious Diseases (NIAID)

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.

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.

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5F31AI162230-03 REVISED

REVISED AWARD: It is the policy of NIH not to prioritize research programs related to diversity, equity and inclusion (DEI) research programs. Therefore, no additional funding will be awarded for this project, and all future years have been removed. UNIVERSITY OF MINNESOTA 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 CFR § 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 05/21/2024. All other terms and conditions still apply to this award.

REVISED AWARD:

This award is revised to reflect increase per budgetary levels effective for the current fiscal year as referenced in the NIH Guide. Copies of the notice may be accessed at the following Internet address: https://grants.nih.gov/funding/searchguide/index.html#/.

This award provides childcare support in the amount of $3,000 per each full-time predoctoral or postdoctoral NRSA trainee appointment slot. These funds are restricted for eligible full-time predoctoral or postdoctoral NRSA trainees for the use of childcare expenses; any unused funds cannot be rebudgeted and must be reported as an unobligated balance on the Federal Financial Report (FFR). See NIH GPS Chapter 11.2.9.7.

A separate report is required under section G.1, Special Reporting Requirements, as part of the RPPR. The attachment must specify the number of trainees who used childcare costs in the reporting period.

Supersedes previous Notice of Award dated **01Y30Y2024**. All other terms and conditions still apply to this award.

Should this fellowship terminate early, a Ruth L. Kirschstein National Research Service Award (NRSA) Termination Notice (PHS 416-7) must be submitted immediately following the termination of support.

Per NIH Policy, submit the Termination Notice via xTrain (era Commons)

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-026.html

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This award reflects the stipend, institutional allowance, and tuition and fees amount(s) effective for the current fiscal year as referenced in the NIH Guide: https://grants.nih.gov/funding/searchguide/index.html#/

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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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Research conducted at the following site(s) must be reported in the Research Performance Progress Report (RPPR), Section G.9 (Foreign component):

Uganda National Council for Science and Technology - UGANDA
Infectious Diseases Institute - UGANDA

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SPREADSHEET SUMMAR/
AWARD NUMBER: 5F31AI162230-03 REVISED

INSTITUTION: UNIVERSITY OF MINNESOTA

Budget	Year 3
Institutional Allowance	$4,750
Other	$16,000
Childcare Costs	$3,000
Stipends	$28,224
TOTAL FEDERAL DC	$51,974
TOTAL FEDERAL F&A	$0
TOTAL COST	$51,974

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/21/2025 12:01 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# F31DK136330
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF NEW MEXICO
1 UNIVERSITY OF NEW MEXICO
SPONSORED PROJECTS OFFICE
ALBUQUERQUE, NM 87131

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1856000642A1

4. Employer Identification Number (EIN)
856000642

5. Data Universal Numbering System (DUNS)
829868723

6. Recipient's Unique Entity Identifier
G389MFAYJNG9

7. Project Director or Principal Investigator
Randy Ko, BS

rko@salud.unm.edu
505-301-8680

8. Authorized Official
STACY M CATANACH
HSC-preaward@salud.unm.edu
505-272-6264

Federal Agency Information

9. Awarding Agency Contact Information
Aricia M Ajose

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
ajosea@mail.nih.gov
301-594-9023

10. Program Official Contact Information
Thomas Artis Boddie
Health Science Policy Analyst
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
thomas.boddie@nih.gov
(301) 402-3137

Federal Award Information

11. Award Number
5F31DK136330-02

12. Unique Federal Award Identification Number (FAIN)
F31DK136330

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Role of GPER in Obesity and Lipid Metabolism.

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases 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 05/01/2024 **– End Date** 04/28/2025	
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	$45,574
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$45,574
26. Project Period Start Date 05/01/2023 **– End Date** 04/28/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$89,868

28. Authorized Treatment of Program Income

29. Grants Management Officer - Signature
Dee Doherty

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: 4/29/2025 12:02 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 5F31DK136330-02 REVISED

Principal Investigator(s):
Randy Ko, BS

Award e-mailed to: HSC-Preaward@salud.unm.edu

Fellow's e-mail:
Randy Ko rko@salud.unm.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR 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 Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number F31DK136330. 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,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$4,750
Other	$12,600

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:02 AM

Stipends	$28,224
Federal Direct Costs	$45,574
Total Award	$45,574
Total Amount of Federal Funds Authorized (Federal Share)	$45,574
TOTAL FEDERAL AWARD AMOUNT	$45,574
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$45,574	$45,574

Fiscal Information:

Payment System Identifier:	1856000642A1
Document Number:	FDK136330A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
DK	8472294	$45,574

NIH Administrative Data:
PCC: MTB TRNG / **OC:** 41013 / **Released:** 2025-04-28
Award Processed: 04/29/2025 00:02:02 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5F31DK136330-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm.

SECTION III – STANDARD TERMS AND CONDITIONS – 5F31DK136330-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain
references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:02 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) F31DK136330. 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.

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.

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 5F31DK136330-02 REVISED

Award Termination:
It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed. University of New Mexico Health Sciences Center 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.

NRSA Stipend Levels and Other Budgetary Information
This award is issued in accordance with the NRSA Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024 described in the NIH Guide Notice NOT-OD-24-104.

Change of Institution (Relocation)
Recipient Institutions should be aware of NIDDK's practice regarding change of institution (relocation) for fellowship awards: https://www.niddk.nih.gov/research-funding/training-career-development/frequently-asked-questions/instructions-requesting-relocation-transfer-fellowships.

SPREADSHEET SUMMARY
AWARD NUMBER: 5F31DK136330-02 REVISED

INSTITUTION: UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR

Budget	Year 2
Institutional Allowance	$4,750
Other	$12,600
Stipends	$28,224
TOTAL FEDERAL DC	$45,574
TOTAL FEDERAL F&A	$0
TOTAL COST	$45,574

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:02 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# F31DK136335
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
Alexis Elizabeth Adrian, BA

aeadrian@wisc.edu
952-388-9959

8. Authorized Official
BRENDA EGAN
baegan@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Aricia M Ajose

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
ajosea@mail.nih.gov
301-594-9023

10. Program Official Contact Information
Thomas Artis Boddie
Health Science Policy Analyst
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
thomas.boddie@nih.gov
(301) 402-3137

Federal Award Information

11. Award Number
5F31DK136335-02

12. Unique Federal Award Identification Number (FAIN)
F31DK136335

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Examining the role of defective oxidative phosphorylation in the normal and diseased prostate

15. Assistance Listing Number
93.847

16. Assistance Listing Program Title
Diabetes, Digestive, and Kidney Diseases 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 04/01/2024 **– End Date** 03/31/2025	
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	$38,608
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$38,608
26. Project Period Start Date 04/01/2023 **– End Date** 03/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$75,936

28. Authorized Treatment of Program Income

29. Grants Management Officer - Signature
Dee Doherty

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: 4/29/2025 12:04 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

SECTION I – AWARD DATA – 5F31DK136335-02 REVISED

Principal Investigator(s):
Alexis Elizabeth Adrian, BA

Award e-mailed to: NIH@rsp.wisc.edu

Fellow's e-mail:
Alexis Elizabeth Adrian aeadrian@wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 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 Of Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number F31DK136335. 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,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$4,750
Other	$5,634

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:04 AM

Stipends	$28,224
Federal Direct Costs	$38,608
Total Award	$38,608
Total Amount of Federal Funds Authorized (Federal Share)	$38,608
TOTAL FEDERAL AWARD AMOUNT	$38,608
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$38,608	$38,608

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	FDK136335A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
DK	8472294	$38,608

NIH Administrative Data:
PCC: MTB TRNG / **OC:** 41013 / **Released:** 2025-04-28
Award Processed: 04/29/2025 00:04:11 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5F31DK136335-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm.

SECTION III – STANDARD TERMS AND CONDITIONS – 5F31DK136335-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain
references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:04 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) F31DK136335. 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.

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.

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – DK SPECIFIC AWARD CONDITIONS – 5F31DK136335-02 REVISED

Award Termination:
It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed. University of Wisconsin - Madison 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.

REVISION #1: This award is revised in accordance with the fiscal policies described in the NIH Guide Notice NOT-OD-24-104, NRSA Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024. Future years have been adjusted accordingly.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ALSO APPLY TO THIS AWARD:

Continuing Resolution
NIH is currently operating under a Continuing Resolution (See NIH Guide Notice NOT-OD-24-073). All legislative mandates that were in effect in FY2023 (see NOT-OD-23-072) remain in effect under this CR. See the Salary Cap Summary for the current and historical record of the salary cap, including effective dates. The Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees are described in NOT-OD-23-076.

Change of Institution (Relocation)
Recipient Institutions should be aware of NIDDK's practice regarding change of institution (relocation) for fellowship awards: https://www.niddk.nih.gov/research-funding/training-career-development/frequently-asked-questions/instructions-requesting-relocation-transfer-fellowships.

Model Organism Sharing Plan
The grantee is required to follow the model organism sharing plan dated March 10, 2023 in the Just In Time Documents and may not implement any changes in the plan without the written prior approval of the NIDDK.

SPREADSHEET SUMMARY
AWARD NUMBER: 5F31DK136335-02 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 2
Institutional Allowance	$4,750
Other	$5,634
Stipends	$28,224
TOTAL FEDERAL DC	$38,608
TOTAL FEDERAL F&A	$0
TOTAL COST	$38,608

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/29/2025 12:04 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# F31MD017471
Federal Award Date
04/29/2025

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
Zachary Dyer, MPH

Zachary.Dyer1@umassmed.edu
7742532220

8. Authorized Official
Amy Miarecki

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
Nancy Lynne Jones
Health Scientist Administrator
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
jonesna@mail.nih.gov
301-594-8945

Federal Award Information

11. Award Number
5F31MD017471-02

12. Unique Federal Award Identification Number (FAIN)
F31MD017471

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Outlining Shadows of Structural Racism Using Publicly Available Social Determinants of Health Data

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 08/31/2025	
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	$48,994
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$48,994
26. Project Period Start Date 09/01/2022 **– End Date** 08/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$80,512

28. Authorized Treatment of Program Income

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: 4/30/2025 12:03 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5F31MD017471-02 REVISED

Principal Investigator(s):
Zachary Dyer, MPH

Award e-mailed to: Research.Funding@umassmed.edu

Fellow's e-mail:
Zachary Dyer Zachary.Dyer1@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 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 Minority Health And Health Disparities of the National Institutes of Health under Award Number F31MD017471. 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)

Institutional Allowance	$4,750
Other	$16,000

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:03 AM

Stipends	$28,244
Federal Direct Costs	$48,994
Total Award	$48,994
Total Amount of Federal Funds Authorized (Federal Share)	$48,994
TOTAL FEDERAL AWARD AMOUNT	$48,994
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$48,994	$48,994

Fiscal Information:

Payment System Identifier:	1043167352A1
Document Number:	FMD017471A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
MD	8020239	$48,994

NIH Administrative Data:
PCC: CPS07NJ / **OC:** 41013 / **Released:** 2025-04-29
Award Processed: 04/30/2025 00:03:01 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5F31MD017471-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm.

SECTION III – STANDARD TERMS AND CONDITIONS – 5F31MD017471-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain
references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 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).

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) F31MD017471. 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.

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 – MD SPECIFIC AWARD CONDITIONS – 5F31MD017471-02 REVISED

It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed. University of Massachusetts 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.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ALSO APPLY TO THIS AWARD:

RESTRICTION: This award may not continue beyond the completion of all doctoral degree requirements. Support for this fellowship will end upon the receipt of a doctoral degree. No funds may be drawn down after the receipt of a doctoral degree. A termination notice must be submitted to the National Institutes of Health upon receipt of a doctoral degree.

REQUIREMENT: This award is subject to the conditions set forth in PA-21-052, Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity), 10/28/2020, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address:
http://grants.nih.gov/grants/guide/pa-files/PA-21-051.html

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:03 AM

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

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.

SPREADSHEET SUMMARY
AWARD NUMBER: 5F31MD017471-02 REVISED

INSTITUTION: Univ of Mass Chan Medical School

Budget	Year 2
Institutional Allowance	$4,750
Other	$16,000
Stipends	$28,244
TOTAL FEDERAL DC	$48,994
TOTAL FEDERAL F&A	$0
TOTAL COST	$48,994

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:03 AM

From: Bulls, Michelle G. (NIH/OD) [E]
To: wshen7@buffalo.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: grantsandcontracts@med.cornell.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Gunsul, Aleta R.
Weill Medical Coll Of Cornell Univ
grantsandcontracts@med.cornell.edu

Dear Gunsul, Aleta R.:

Effective with the date of this letter, funding for Project Number 5K12HD000850-40 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: thompslm@ored.rutgers.edu
Subject: Grant Termination Notification
Date: Tuesday, April 1, 2025 9:23:00 AM
Attachments: image002.png

4/1/2025

Thompson, Latona M
Rutgers Biomedical And Health Sciences
thompslm@ored.rutgers.edu

Dear Thompson, Latona M:

Effective with the date of this letter, funding for Project Number 5K22CA258675-03 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with 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)

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P50HD112034
Federal Award Date
05/21/2025

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)
1946036493A1

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
Adrian Erlebacher, MD
Professor
Adrian.Erlebacher@ucsf.edu
415-502-3583

8. Authorized Official
Gordon Shettle

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
TRAVIS JOHN Kent
Program Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
travis.kent@nih.gov
301) 435-2295

Federal Award Information

11. Award Number
5P50HD112034-03

12. Unique Federal Award Identification Number (FAIN)
P50HD112034

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Immunological, epigenetic and developmental determinants of early pregnancy success

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

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 05/01/2025 **– End Date** 04/30/2026	
20. Total Amount of Federal Funds Obligated by this Action	$1,650,001
20 a. Direct Cost Amount	$1,165,138
20 b. Indirect Cost Amount	$484,863
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,650,001
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,650,001
26. Project Period Start Date 08/01/2023 **– End Date** 04/30/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$5,065,840

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Mahasin Ingram

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: 5/21/2025 2:08 PM

Notice of Award

SPECIALIZED RESEARCH CENTER
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P50HD112034-03

Principal Investigator(s):
Adrian Erlebacher, MD

Award e-mailed to: cgrasteam@ucsf.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,650,001 (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 Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P50HD112034. 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,

Mahasin Ingram
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/21/2025 2:08 PM

Salaries and Wages	$408,238
Fringe Benefits	$115,307
Personnel Costs (Subtotal)	$523,545
Materials & Supplies	$82,801
Travel	$17,962
Other	$157,801
Subawards/Consortium/Contractual Costs	$376,743
Publication Costs	$6,286
Federal Direct Costs	$1,165,138
Federal F&A Costs	$484,863
Approved Budget	$1,650,001
Total Amount of Federal Funds Authorized (Federal Share)	$1,650,001
TOTAL FEDERAL AWARD AMOUNT	$1,650,001
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,650,001

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,650,001	$1,650,001
4	$1,650,000	$1,650,000
5	$1,650,001	$1,650,001

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1946036493A1
Document Number:	PHD112034A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025	2026	2027
HD	8014706	$1,650,001	$1,650,000	$1,650,001

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: FI -TK / **OC**: 41025 / **Released**: 05/20/2025
Award Processed: 05/21/2025 02:08:05 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P50HD112034-03

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 – 5P50HD112034-03

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.)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/21/2025 2:08 PM

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 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) P50HD112034. 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: 5/21/2025 2:08 PM

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

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5P50HD112034-03

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.

RESTRICTION: $50,000 direct costs and the associated Facilities and Administrative expenses are provided for the pilot project "Characterization of the human maternal-fetal interface transcriptome at the single cell level in mid-gestation." The project is under the direction of Dr. Alicia Bárcena. If not all the direct costs are required for the collaborative project, then the funds may only be re-budgeted to a different pilot/collaborative project with the approval of the NICHD.

NON-SNAP: NIH staff has determined that the submitted Research Performance Progress Report is within the approved scope of work.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety 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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/21/2025 2:08 PM

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".

SALARY CAP: No award funds shall be used to pay the salary of an individual at a rate in excess of the current salary cap. This award has been adjusted accordingly See NIH Guide Notice NOT-OD-25-085.

SUBPROJECTS: Subproject funding information is available via the NIH RePORTER System.

GENOMIC DATA SHARING PLAN: Dissemination of study data will be in accordance with the recipient's accepted genomic data sharing plan as stated in the application dated 07/28/2022. Failure to comply with the sharing plan as mutually agreed upon by the recipient and NICHD may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Guide Notice NOT-OD-14-124.

NOFO: This award is subject to the requirements indicated in HD23-011 which are hereby incorporated by reference. See the NIH Funding site for more information.

RESTRICTION: $50,000 direct costs and the associated Facilities and Administrative expenses are provided for community outreach/education purposes. These funds are restricted and may not be used for any other purpose without the written prior approval of the NICHD.

REQUIREMENT: Future pilot projects must go through an internal administrative review process.

PILOT PROJECTS: Institutions with NCTRI centers will provide the NICHD with a description of the review procedures for all pilot and collaborative projects in the upcoming Progress Report. This should include information regarding how a particular project was selected and evaluated for funding. The use of standing advisory committees, both internal and external, is particularly encouraged for this process. Pilot projects that are directed by new PIs or PIs who are not associated with the center are encouraged as are collaborative projects between centers.

Before the pilot project is funded, an institutionally-approved application that conforms with a R03-type proposal must be provided to the NICHD. It should include the following using the SF 424 R&R Application format. ·

- Appropriate IRB and/or IACUC approvals ·
- Human subjects education training certifications for new key researchers involved with human subjects work
- Other Support for new key researchers, if applicable ·
- A budget and budget justification
- A statement that the work will not violate any federal regulations, e.g., the Dickey
- Wicker amendment.

SPREADSHEET SUMMARY
AWARD NUMBER: 5P50HD112034-03

INSTITUTION: The Regents of the UCSF

Budget	Year 3	Year 4	Year 5
Salaries and Wages	$408,238	$380,405	$386,396
Fringe Benefits	$115,307	$103,493	$105,498
Personnel Costs (Subtotal)	$523,545	$483,898	$491,894
Materials & Supplies	$82,801	$78,753	$78,975
Travel	$17,962	$17,740	$17,804
Other	$157,801	$136,176	$136,656
Subawards/Consortium/Co	$376,743	$475,064	$453,171

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/21/2025 2:08 PM

ntractual Costs			
Publication Costs	$6,286	$6,209	$6,231
TOTAL FEDERAL DC	$1,165,138	$1,197,840	$1,184,731
TOTAL FEDERAL F&A	$484,863	$452,160	$465,270
TOTAL COST	$1,650,001	$1,650,000	$1,650,001

Facilities and Administrative Costs	Year 3	Year 4	Year 5
F&A Cost Rate 1	61.5%	61.5%	61.5%
F&A Cost Base 1	$788,395	$735,219	$756,536
F&A Costs 1	$484,863	$452,160	$465,270

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/21/2025 2:08 PM

National Institutes of Health
Office of Extramural Research

3/21/2025

Nino N Campos
Northwestern University At Chicago
SponsoredResearch@northwestern.edu

Dear Nino N Campos:

Effective with the date of this letter, funding for Project Number 5R01AA029044-04 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 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.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *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

[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

From: Bulls, Michelle G. (NIH/OD) [E]
To: bullockr@umd.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Bullock, Rose
Univ Of Maryland, College Park
bullockr@umd.edu

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)

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Militano, Jeni (NIH/NIA/ERP) [E]
Subject: FW: Grant Termination Notification
Date: Friday, March 21, 2025 1:56:23 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 12:28 PM
To: cassie.martin@bannerhealth.com
Subject: Grant Termination Notification

3/21/2025

Cassie Martin
Banner Health
cassie.martin@bannerhealth.com

Dear Cassie Martin:

Effective with the date of this letter, funding for Project Number 5R01AG063954-05 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 7/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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 Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4]

NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG077672
Federal Award Date
04/22/2025

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

8. Recipient's Unique Entity Identifier
VGJHK59NMPK9

q. Project Director or Principal Investigator
Jennifer Nicole Rauch, PHD
Assistant Professor
rauch@umass.edu
906-869-2169

j . Authorized Official
Carol Sprague
sprague@research.umass.edu

Federal Agency Information

9. Awarding Agency Contact Information
JERMAIN Cooper

NATIONAL INSTITUTE ON AGING
jermain.cooper@nih.gov
301-496-1472

10. Program Official Contact Information
Austin Jyan-Yu Yang
Health Scientist Administrator
NATIONAL INSTITUTE ON AGING
yangj13@mail.nih.gov
301.496.9350

Federal Award Information

11. Award Number
5R01AG077672-04

12. Unique Federal Award Identification Number (FAIN)
R01AG077672

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Deciphering the Molecular Features Underlying LRP1-Mediated Tau Spread

15. Assistance Listing Number
93.866

18. Assistance Listing Program Title
Aging Research

1q. Award Action Type
Non-Competing Continuation (REVISED)

1j . Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2025 **– End Date** 03/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	($-38,746)
20 a. Direct Cost Amount	$-25,000
20 b. Indirect Cost Amount	$-13,746
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$348,714
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$348,714
28. Project Period Start Date 06/01/2022 **– End Date** 03/31/2027	
2q. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,652,858

2j . 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: 4/22/2025 12:08 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG0qq8q2-04 REVISED

Principal Investigator(s):
Jennifer Nicole Rauch, PHD

Award e-mailed to: opam@umass.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect a decrease in the amount of $38,746 (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 On Aging of the National Institutes of Health under Award Number R01AG077672. 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)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/22/2025 12:08 AM

Federal Direct Costs	$225,000
Federal F&A Costs	$123,714
Approved Budget	$348,714
Total Amount of Federal Funds Authorized (Federal Share)	$348,714
TOTAL FEDERAL AWARD AMOUNT	$348,714
AMOUNT OF THIS ACTION (FEDERAL SHARE)	($-38,746)

SUMMAR/ TOTALS FOR ALL / EARS (for this Document Number)		
/ R	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$348,714	$348,714
5	$386,865	$386,865

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: RAG077672A
PMS Account Type: P (Subaccount)
Fiscal / ear: 2025

IC	CAN	2025	2026
AG	8033159	$348,714	$386,865

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 3BSETAY / **OC**: 41025 / **Released**: 04/21/2025
Award Processed: 04/22/2025 12:08:56 AM

SECTION II – PA/ MENTY HOTLINE INFORMATION – 5R01AG0qq8q2-04 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 – 5R01AG0qq8q2-04 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: 4/22/2025 12:08 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) R01AG077672. 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.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/22/2025 12:08 AM

Treatment of Program Income:
Additional Costs

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – AG SPECIFIC AWARD CONDITIONS – 5R01AG0qq8q2-04 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.

NIH is currently operating under a Continuing Resolution (see NIH Guide Notice NOT-OD-25-054). Therefore, this non-competing award has been made at 90% of the level indicated for this budget period on the prior Notice of Award. If the final appropriation permits, adjustments may be made up to the FY2025 funding plan level. All legislative mandates that were in effect in FY 2024 (see NOT-OD-24-110) remain in effect under the CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see NOT-OD-24-104).

Supersedes Notice of Award issued 03/14/2025. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at a level not to exceed the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein National Research Service Award stipend in effect at the time of the competing award). Support recommended for future years has been adjusted accordingly, if applicable. The full guide Notice describing the level of compensation allowed for a graduate student can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

SPREADSHEET SUMMAR/
AWARD NUMBER: 5R01AG077672-04 REVISED

INSTITUTION: UNIVERSITY OF MASSACHUSETTS AMHERST

Budget	Year 4	Year 5
TOTAL FEDERAL DC	$225,000	$250,000
TOTAL FEDERAL F&A	$123,714	$136,865
TOTAL COST	$348,714	$386,865

Facilities and Administrative Costs	Year 4	Year 5

F&A Cost Rate 1	59.5%	59.5%
F&A Cost Base 1	$207,923	$230,025
F&A Costs 1	$123,714	$136,865

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/22/2025 12:08 AM

From: Bulls, Michelle G. (NIH/OD) [E]
To: nick.novak@wisc.edu
Subject: Grant Termination Notification
Date: Monday, March 24, 2025 3:51:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/24/2025

Nick Novak
University Of Wisconsin-Madison
nick.novak@wisc.edu

Dear Nick Novak:

Effective with the date of this letter, funding for Project Number 5R01AI158463-04 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 8/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations

imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.* [8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

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]

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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]

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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

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

March 10, 2025

Zulma Montesinos
The Regents of the University of California,
San Francisco,
521 Parnassus Ave
San Francisco, CA 94143-0000

Dear Ms. Montesinos,

Funding for Project Number 5R01AI166967-03 is hereby terminated pursuant to the [INSERT APPROPRIATE GPS CITATION TO MATCH AWARD DATE) 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 05/10/2023, 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5R01AI166967-03 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-156.
[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,

Emily Linde
Director, Grants Management Program
National Institutes of Allergy and Infectious Diseases

[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).

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

March 10, 2025

Zulma Montesinos
The Regents of the University of California,
San Francisco,
521 Parnassus Ave
San Francisco, CA 94143-0000

Dear Ms. Montesinos,

Funding for Project Number 5R01AI166967-03 is hereby terminated pursuant to the [INSERT APPROPRIATE GPS CITATION TO MATCH AWARD DATE) 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 05/10/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

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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 5R01AI166967-03 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-156.
[6] 2024 Policy Statement at IIA-156.

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Administrative Appeal

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Sincerely,

Emily Linde
Director, Grants Management Program
National Institutes of Allergy and Infectious Diseases

[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).

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

March 10,2025

University of San Francisco

2130 Fulton Avenue

San Francisco, CA 94117

Camille Coley

Funding for Project Number 5R01AI169239-03 is hereby terminated pursuant to the 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5R01AI169239-03 is incompatible

[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-156.
[6] 2024 Policy Statement at IIA-156.

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,

Emily Linde

Director, Grants Management Program

National Institutes of Allergy and Infectious Diseases

[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).

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

March 10,2025

University of San Francisco

2130 Fulton Avenue

San Francisco, CA 94117

Camille Coley

Funding for Project Number 5R01AI169239-03 is hereby terminated pursuant to the 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5R01AI169239-03 is incompatible

[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-156.
[6] 2024 Policy Statement at IIA-156.

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]

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Sincerely,

Emily Linde

Director, Grants Management Program

National Institutes of Allergy and Infectious Diseases

[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).

National Institutes of Health
Office of Extramural Research

03/20/2025

Magdalene Cho
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
cgrasteam@ucsf.edu

Dear Magdalene Cho:

Effective with the date of this letter, funding for Project Number 5R01DA052016-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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, on behalf Pamela Fleming, Chief Grants Management Officer, National Institute on Drug Abuse
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)

University of California, San Francisco 533

Parnassus Avenue, UC Hall 350

San Francisco, CA 94143-0634

March 10, 2025

Catherine Chan:

Funding for Project Number 5 R01 EY028739-07 is hereby terminated pursuant to the National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5

[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.

R01 EY028739-07 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]

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Sincerely,

Karen Robinson Smith

Chief, Grants Management Officer

Division of Extramural Activities

National Eye Institute

Office: (301) 435-8178

kyr@nei.nih.gov

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[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).

University of California, San Francisco 533

Parnassus Avenue, UC Hall 350

San Francisco, CA 94143-0634

March 10, 2025

Catherine Chan:

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[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.

R01 EY028739-07 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]

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Sincerely,

Karen Robinson Smith

Chief, Grants Management Officer

Division of Extramural Activities

National Eye Institute

Office: (301) 435-8178

kyr@nei.nih.gov

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[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).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

March 10, 2025

Sarah Toov
Health Partners Institute
8170 33rd Ave. S.
Minneapolis, MN 55425

Ms. Toov,

Funding for Project Number 5R01HD107753-03 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 05/21/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5R01HD107753-03 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

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,

Lauren Ruane
Deputy Branch Chief
Grants Management Branch
Eunice Kennedy Shriver National Institute of Child Health and Human Development

[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).

From: Bulls, Michelle G. (NIH/OD) [E]
To: nga@umaryland.edu
Cc: Agresti, Anthony (NIH/NHLBI) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]
Subject: Immediate Attention Required - Termination Letter
Date: Thursday, March 20, 2025 4:50:09 PM
Attachments: Termination Letter_5R01HL165686 03_3.19.25.pdf

Please see attached.

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)

National Institutes of Health
Office of Extramural Research

03/20/2025

Lester Warnac Villaflor
UNIVERSITY OF WASHINGTON
gcsfund@uw.edu

Dear Lester Warnac Villaflor:

Effective with the date of this letter, funding for Project Number 5R01LM013301-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

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[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 Andrea Culhane, Chief Grants Management Officer,
National Library of Medicine
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Grant, Priscilla (NIH/NIMHD) [E]
Subject: FW: Grant Termination Notification
Date: Tuesday, April 1, 2025 10:15:53 AM
Attachments: image001.jpg
image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Tuesday, April 1, 2025 9:24 AM
To: awards@foundation.sdsu.edu
Subject: Grant Termination Notification

4/1/2025

Amison, Jennie
San Diego State University
awards@foundation.sdsu.edu

Dear Amison, Jennie:

Effective with the date of this letter, funding for Project Number 5R01MD016880-03 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 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy

these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with 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, 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)

3/21/2025

Rhodes, Carol
University Of Washington
osp@uw.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 5R01MD017573-03 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 12/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why

an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: osp@uw.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Rhodes, Carol
University Of Washington
osp@uw.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 5R01MD017573-03 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 12/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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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

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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)

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 5R01MD018679-02 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 01/01/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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

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[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]

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Sincerely,

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: wbsteele@uab.edu
Subject: Grant Termination Notification
Date: Tuesday, April 1, 2025 9:23:00 AM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/1/2025

Steele, William
University Of Alabama At Birmingham
wbsteele@uab.edu

Dear Steele, William:

Effective with the date of this letter, funding for Project Number 5R01MD019235-02 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 3/1/2024, 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. It is the policy of NIH not to prioritize research activities that focuses gaining scientific knowledge on why individuals are hesitant to be vaccinated and/or explore ways to improve vaccine interest and commitment. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with 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)

03/20/2025

Peter Dale
PUBLIC HEALTH FOUNDATION ENTERPRISES
pdale@helunahealth.org

Dear Peter Dale:

Effective with the date of this letter, funding for Project Number 5R01MH119956-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 04/26/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: cballwanz@umaryland.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

NIH National Institutes of Health
Office of Extramural Research

3/21/2025

Christine R. Toalepai
University Of Maryland Baltimore
cballwanz@umaryland.edu

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)

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 *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, 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

[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).

From: Bulls, Michelle G. (NIH/OD) [E]
To: jdalrym2@jhu.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Dalrymple, Jordan
Johns Hopkins University
jdalrym2@jhu.edu

Dear Dalrymple, Jordan:

Effective with the date of this letter, funding for Project Number 5R21HD114341-02 is hereby terminated pursuant to the Fiscal Year 2025 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2025 Policy Statement applies to your project because NIH approved your grant on 1/1/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is

incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: oconnellr@uchicago.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

O'Connell, Ryan
University Of Chicago
oconnellr@uchicago.edu

Dear O'Connell, Ryan:

Effective with the date of this letter, funding for Project Number 5R21MD018707-02 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 3/1/2024, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: pdale@phfe.org
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Peter David Dale
Public Health Foundation Enterprises
pdale@phfe.org

Dear Peter David Dale:

Effective with the date of this letter, funding for Project Number 5R25MH119858-05 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 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 -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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: ALEX.FRANZ@CUANSCHUTZ.EDU
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

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

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)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Notice of Award
FAIN# U01DK137272
Federal Award Date
05/01/2025

Recipient Information

1. Recipient Name
THE REGENTS OF THE UNIV. OF COLORADO
13001 E 17TH PL STE F428
AURORA, CO 80045

2. Congressional District of Recipient
06

7. 3aPment SPstem Identifier yID(
1846000555A7

) . 4mploPer Identification NumEer y4IN(
846000555

b. Data 5niversal NumEering SPstem yD5NS(
041096314

U. Recipient6s 5ni' ue 4ntitP Identifier
MW8JHK6ZYEX8

q. 3roject Director or 3rincipal Investigator
Lilia Cervantes, MD (Contact)
Associate Professor
lilia.cervantes@cuanschutz.edu
303-641-8009

8. Authorized Official
Garrett M Steed

Federal AgencP Information

9. Awarding AgencP Contact Information
Lesley Whipp
Grants Specialist
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
whipplc2@niddk.nih.gov
301-443-9360

10. 3rogram Official Contact Information
JENNIFER MICHELLE Norton

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
jenna.norton@nih.gov
301-451-7314

Federal Award Information

11. Award NumEer
5U01DK137272-02

12. 5ni' ue Federal Award Identification NumEer yFAIN(
U01DK137272

17. StatutorP AuthoritP
42 USC 241 31 USC 6305 42 CFR 52

1) . Federal Award 3roject Title
NAVIGATE Kidney: A Multi-Level Intervention to Reduce Kidney Health Disparities

1b. Assistance Listing NumEer
93.847

1U. Assistance Listing 3rogram Title
Diabetes, Digestive, and Kidney Diseases Extramural Research

1q. Award Action TPpe
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

SummarP Federal Award Financial Information	
19. Budget 3eriod Start Date 07/01/2024 **– 4nd Date** 04/30/2025	
20. Total Amount of Federal Funds OEligated EP this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
27. Total Amount of Federal Funds Obligated this budget period	$736,635
2) . Total Approved Cost Sharing or Matching, where applicaEle	$0
2b. Total Federal and Non-Federal Approved this Budget 3eriod	$736,635
2U. 3roject 3eriod Start Date 09/01/2023 **– 4nd Date** 04/30/2025	
2q. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,113,431

28. Authorized Treatment of 3rogram Income
Additional Costs

29. Grants Management Officer - Signature
Dee Doherty

70. 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 PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

S4CTION I – AWARD DATA – b501DK17q2q2-02 R4VIS4D

3rincipal Investigatorys(:
Lilia Cervantes (contact), MD
Larissa Myaskovsky, PHD

Award e-mailed to: xenia@ucdenver.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF COLORADO DENVER in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 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 Diabetes And Digestive And Kidney Diseases of the National Institutes of Health under Award Number U01DK137272. 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,

Dee Doherty
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Additional information follows

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

Cumulative Award Calculations for this Budget 3eriod y5.S. Dollars(	
Salaries and Wages	$106,078
Fringe Benefits	$32,787
3ersonnel Costs ySuEtotal(	$138,865
Other	$9,445
SuEawards\Consortium\Contractual Costs	$502,231
Federal Direct Costs	$650,541
Federal F&A Costs	$86,094
Approved Budget	$736,635
Total Amount of Federal Funds Authorized yFederal Share(	$736,635
TOTAL F4D4RAL AWARD AMO5NT	$736,635
AMO5NT OF THIS ACTION yF4D4RAL SHAR4(	$0

S5MMAR$ TOTAL F4D4RAL AWARD AMO5NT $4AR y2 ((for this Document Number)	
AWARD N5MB4R	TOTAL F4D4RAL AWARD AMO5NT
5U01DK137272-02	$736,635
3U01DK137272-02S1	$385,046
3U01DK137272-02S2	$186,840
TOTAL	/ 1,708,b21

S5MMAR$ TOTALS FOR ALL $4ARS (for this Document Number)		
$R	THIS AWARD	C5M5LATIV4 TOTALS
2	$736,635	$1,308,521

Fiscal Information:

3aPment SPstem Identifier:	1846000555A7
Document NumEer:	UDK137272A
3MS Account TPpe:	P (Subaccount)
Fiscal $ear:	2024

IC	CAN	2024
DK	8472278	$736,635

NIH Administrative Data:
3CC: KJN KEPT / **OC**: 41029 / **Released**: 04/30/2025
Award 3rocessed: 05/01/2025 12:05:42 AM

S4CTION II – 3A$M4NTYHOTLIN4 INFORMATION – b501DK17q2q2-02 R4VIS4D

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

S4CTION III – STANDARD T4RMS AND CONDITIONS – b501DK17q2q2-02 R4VIS4D

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 yR&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).

Carry over of an unobligated balance into the next budget period requires 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) U01DK137272. 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*.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of 3rogram Income:
Additional Costs

S4CTION IV – DK S34CIFIC AWARD CONDITIONS – b501DK17q2q2-02 R4VIS4D

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 Termination:
It is the policy of NIH not to prioritize research programs related to DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

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, no additional funding will be awarded for this project, and all future years have been removed. University of Colorado Denver 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.

In accordance with NOT-OD-24-109, and the availability of FY2024 appropriated funds, this award provides funding at the 96% committed level.

Salary Cap

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap (Executive Level II). Therefore, this award and/or future years are adjusted accordingly, if applicable. See the Salary Cap Summary for the current and historical record of the salary cap, including effective dates.

Other Support

NIDDK has received the updated other support information provided for all key personnel as identified by the applicant. Only other support information for the PD/PI(s) and any individual(s) named as key personnel on the Notice of Grant Award have been reviewed for overlap. It is the responsibility of the recipient to make sure no overlap of budget, effort, or aims exist for all personnel devoted to this grant.

Prior Approvals with Multiple PI's

In keeping with NOT-OD-11-118, 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.

RESTRICTION: IRB Approval Lacking: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the NIDDK's acceptance of the certification of IRB approval. T**he certification of IRB approval must be submitted to the NIDDK within 6 months from the issue date of this award.**

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 NIDDK's notification to the recipient that the identified issues have been resolved and this restriction removed.

Failure to submit the certification of IRB approval to the NIDDK **within the 6 months period** or to otherwise comply with the above requirements can result in suspension and/or

termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Section 4.1.15 “Human Subjects Protection”, for specific requirements related to the protection of human subjects which are applicable to and a term and condition of this award.

R4STRICTION:
Funds will be restricted for use for administrative activities directly related to establishing the consortium, finalizing the site-specific consortial protocol and obtaining IRB and DSMB approval. No funds can be expended on direct participant recruitment until study is approved to begin enrollment.

Consortium Involvement
This award includes funds awarded for consortium activity for the University of New Mexico HSC, Denver Health and Hospital Authority, Weill Cornell Medical College and Vuela for Health. Consortiums are to be established and administered as described in the NIH Grants Policy Statement.

Human Subjects Enrollment Reporting
The NIH is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Investigators must report sex/gender, race, and ethnicity information using the Human Subjects System (HSS) module in the eRA Commons.

For more information see the NIH Guide Notice NOT-OD-18-179.

Milestones
Future year support is contingent on satisfactory achievement of approved performance milestones. If approved milestones are not achieved fully, NIDDK may request development of a remedial plan and more frequent monitoring of progress or take other remedial actions.

Dissemination of NIH-Funded Clinical Trial Information
The clinical trial(s) supported by this award is subject to the plan in the competing application and the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the Clinical Trials Registration and Results Information Submission regulation at 42 CFR Part 11.

Data and Safety Monitoring Plan
The recipient is required to follow the data and safety monitoring plan included in the application and may not implement any changes in the plan without the written prior approval of the NIDDK. For all trials (including low risk trials where routine program review is based on the annual RPPR), unexpected serious adverse events should be reported to the Program Director at the same time that they are sent to the IRB (i.e., within 7 calendar days of the initial receipt of information for fatal or life-threatening suspected unexpected, serious adverse reactions, and within 15 calendar days of receipt of information for non-fatal, non-life-threatening unexpected, suspected serious adverse reactions). **The annual progress report should provide dates of meetings and action items from all DSMB or other safety monitoring meetings during the previous reporting period (if applicable), any data and safety monitoring issues that have occurred since the previous reporting**

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

period (including any IRB or FDA actions), and a description of any changes in the protocol, consent, or DSMP.

Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and the NIH as defined below.

The Program Director(s)/Principal Investigator(s) will have the primary responsibility for:

1. Developing the research design and study protocol, including definition of objectives and approaches, sample size and power calculations, and establishing procedures for participant recruitment and follow-up, data collection, quality control, interim data and safety monitoring, final data analysis and interpretation, and publication of results.

2. Establishing a Steering Committee to implement, coordinate and manage the project(s). Recipient(s) will name investigators to serve as members on a Steering Committee and other subcommittees, as appropriate, meeting periodically. Recipients will be required to accept and implement the common protocol(s) and procedures approved by the Steering Committee.

3. Designating Protocol Chairs. The Program Directors/Principal Investigators (for studies involving multiple protocols) shall designate a single Protocol Chairperson (if the Program Director/Principal Investigator does not assume this role) for each protocol to be carried out by the study group. The Protocol Chairperson shall function as the scientific coordinator for the protocol and shall assume responsibility for obtaining approval to implement the protocol from the Steering Committee and for developing and monitoring the protocol. Significant modifications to approved protocols must be approved by the Steering Committee.

4. Implementing collection of data specified by the study protocol. For a multi-center study, each recipient/site is required to ensure that data will be submitted expeditiously to the Data Coordinating Center. Additionally, individual investigators/sites must demonstrate the ability to implement the strategy specifically designed for their individual study population.

5. Establishing procedures for data quality, completeness, and security. Recipients are responsible for ensuring accurate and timely assessment of the progress of each study, including development of procedures to ensure that data collection and management are: (1) adequate for quality control and analysis; (2) for clinical trials, as simple as appropriate in order to facilitate cooperation/referral of study participants by physicians to avoid unnecessary expense; and (3) sufficiently staffed across the participating

institutions. For research involving multiple sites, a plan for analysis of pooled data will be developed by the Steering Committee.

6. Submitting interim progress reports, when requested or agreed upon by both parties, to the NIDDK Program Official including as a minimum, summary data on protocol performance. For coordinated multiple awards or a multi-site single award, the NIDDK Program Official may require additional information from individual recipients/sites. Such reports are in addition to the required annual noncompeting continuation progress report.

7. Reporting of the study findings. Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and NIH policies. The recipient must also be adherent to Study Publication and Presentation Policy. The NIDDK will have access to and may periodically review all data generated under an award. NIDDK staff may co-author publications of findings with recipients consistent with NIH and study policies.

8. Any third-party collaboration (including but not limited to interactions with organizations from industry, academia, and nonprofit institutions) should be governed by a research collaboration agreement (e.g., Clinical Trial Agreement, Research Collaborative Agreement, etc.) or any third-party contract mechanism(s) with terms that ensure the collaboration is conducted in accordance with the Cooperative Agreement, applicable NIH/NIDDK policies and procedures, and with written approval from NIDDK Program staff. Any relevant proposed third-party agreements related to the network studies between grantee and third-party will be provided to the NIDDK Program staff and NIDDK Technology Advancement Office for review, comment, and approval to assure compliance with NIH/NIDDK policies and network policies. Further, at the request of the NIDDK Program staff, any other network-relevant third-party agreements must be shared with NIDDK. Failure to comply with this term may prompt action in accordance with NIH Grants Policy Statement, Section 8.5 titled: “Special Award Conditions and Remedies for Noncompliance (Special Award Conditions and Enforcement Actions”, and Section 8.5.2, titled: “Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding Support”, noncompliance with the terms and conditions of award will be considered by the funding IC for future funding and support decisions and may result in termination of the award.”

9. Any involvement of a third-party (including but not limited to industry, academia, and nonprofit institutions) in the study and network activities that includes access to any network generated resources (i.e., data and bio-samples), or study results that are not publicly available, or using the name of the network or study or the name of the NIH or NIDDK, is permitted only after written permission by the NIDDK Program staff who will consult with others at NIH and NIDDK Technology Advancement Office.

10. Maintaining confidentiality of information: The recipient(s) will maintain the confidentiality of the information developed by the investigators (i.e., protocols, data analysis, conclusions, etc.) as well as proprietary information of an individual company or other entity collaborating with the study. Any exception requires written approval from NIDDK Program staff.

11. Data Management and Sharing Plan: In accordance with the NIH Policy for Data Management and Sharing (NIH NOT-OD-21-013), the NIDDK approved plan will become a term and condition of award, be routinely monitored during the award period, and compliance may factor into future funding decisions. By the end of the funding or proprietary period, a recipient or study group may not continue to use or share study generated resources until those resources are available to the public via a NIDDK approved repository per the NIDDK approved plan. The NIDDK has established a Central Repository to support the receipt, storage, and distribution of data, bio-samples,

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

and other resources generated in clinical studies funded by the NIH/NIDDK. When the NIDDK Central Repository is to be utilized, prior to enrolling participants, the PI or his/her designee will coordinate with the NIDDK Program and Central Repository staff to prepare for eventual archiving and distribution of the study generated resources that are to be maintained in the Central Repository. These resources will be available to the wider scientific community in accordance with the NIH Data Management and Sharing policy (http://grants.nih.gov/grants/policy/data_sharing/ and, https://grants.nih.gov/policy/sharing.htm, and http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm), per the NIDDK approved data management and sharing plan..

12. Study investigators are required to publish and to release publicly and disseminate results and other products of the study, in accordance with study protocols, steering committee policies on publications, and the NIDDK approved sharing plan.

13. Study investigators are required to comply with NIH Policy on the Dissemination of NIH Funded Clinical Trial Information as stated at https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm. Per policy, the recipient is responsible for meeting the expectations of this policy. Refer to additional information at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

An NIDDK Project Scientist with substantial involvement will:

1. Serve as the contact point for all facets of the scientific interaction with the recipient (s). As required for the coordination of activities and to expedite progress, NIDDK may designate additional NIDDK staff to provide advice to the recipient on specific scientific and/or analytic issues. Such staff may include another Project Scientist or Project Coordinator, who will provide direct technical assistance to the recipients to optimize the conduct and/or analysis of the study; or who may assist in the coordination of activities across multiple sites.

2. For multi-center studies, participate in the Steering Committee that oversees study conduct. The NIDDK Project Scientist or Project Coordinator will be a full participant and voting member of the Steering Committee and, if applicable, subcommittees.

3. Serve as a resource to study investigators with respect to other ongoing NIDDK activities that may be relevant to the study to facilitate compatibility with the NIDDK missions and avoid unnecessary duplication of effort.

4. Have substantial involvement assisting in the design and coordination of research activities for recipients as elaborated below:

a. Assisting by providing advice in the management and technical performance of the investigations, coordinating required regulatory clearances for investigational agents used in the study, which are held by NIDDK. The NIDDK may reserve the right to cross file or independently file an Investigational New Drug Application or an Investigational Device Exemption form with the FDA.

b. The NIDDK Project Scientist or Project Coordinator may coordinate activities among recipients by assisting in the design, development, and coordination of a common research or clinical protocol and statistical evaluations of data; in the preparation of questionnaires and other data recording forms; and in the publication of results.

c. Reviewing procedures for assessing data quality and study performance monitoring.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

d. The NIDDK Project Scientist or Project Coordinator may be co-authors on study publications. In general, to warrant co-authorship, NIDDK staff must have contributed to the following areas: (a) design of the concepts or experiments being tested; (b) performance of significant portions of the activity; (c) participation in analysis and interpretation of study results and (d) preparation and authorship of pertinent manuscripts.

The NIDDK Program Official identified in the Notice of Award will:

1. Interact with the Program Director(s)/Principal Investigator(s) on a regular basis to monitor study progress. Monitoring may include: regular communications with the Program Director/Principal Investigator and staff, periodic site visits, observation of field data collection and management techniques, quality control, fiscal review, and other relevant matters; as well as attendance at Steering Committee, data safety and monitoring board, and related meetings. The NIDDK retains, as an option, periodic review of progress by researchers not involved with the study.
2. Review and approve protocols prior to implementation to insure they are within the scope of peer review, for safety considerations, as required by Federal regulations.
3. The NIDDK Program Official will monitor protocol progress, and may request that a protocol study be closed to accrual for reasons including: (a) accrual rate insufficient to complete study in a timely fashion; (b) accrual goals met early; (c) poor protocol performance; (d) patient safety and regulatory concerns; (e) study results that are already conclusive; (f) low likelihood of showing a benefit of the intervention (futility); and (g) emergence of new information that diminishes the scientific importance of the study question. The NIDDK will not permit further expenditures of NIDDK funds for a study after requesting closure except as specifically approved by the NIDDK.
4. Make recommendations for continued funding based on: a) overall study progress, including sufficient patient and/or data accrual; b) cooperation in carrying out the research (e.g., attendance at Steering Committee meetings, implementation of group decisions, compliance with the terms of award and reporting requirements); and/or c) maintenance of a high quality of research, which will allow pooling of data and comparisons across multiple cooperative agreement awards for common data elements.
5. Appoint an independent Data and Safety Monitoring Board (DSMB) as appropriate for Phase III clinical trials or other high-risk studies, or an Observational Study Monitoring Board (OSMB) for observational/epidemiologic studies; these Boards will review study progress, safety data, and interim results, as appropriate, and provide guidance to the NIDDK. The NIDDK Program Official or their Project Coordinator will serve as the Executive Secretary and/or NIDDK program representative on the DSMB/OSMB.

Areas of Joint Responsibility include:

In addition to the interactions defined above, NIDDK Project Scientist and Recipients shall share responsibility for the following activities:

Steering Committee

A Steering Committee organized by the study investigator(s) will be the main governing body of the study.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

The Steering Committee has primary responsibility to design research activities, establish priorities, develop common protocols and manuals, questionnaires and other data recording forms, establish and maintain quality control among recipients, review progress, monitor patient accrual, coordinate and standardize data management, and cooperate on the publication of results. Major scientific decisions regarding the core data will be determined by the Steering Committee. The Steering Committee will document progress in written reports to the NIDDK Program Official, and will provide periodic supplementary reports upon request.

The Steering Committee will be composed of all Program Director(s)/Principal Investigator(s), (including those of data coordinating /statistical centers, if any) and co-investigators as deemed necessary, and the NIDDK Project Scientist. The final structure of the Steering Committee and voting procedures will be established at the first meeting. The NIDDK Project Scientist will have voting membership on the Steering Committee, and as appropriate, its subcommittees. The frequency of Steering Committee meetings will be dictated by a vote of the members of the Steering Committee. The NIDDK Program Official may serve as a non-voting member on the Steering Committee.

A Chairperson of the Steering Committee will be selected and voted on by the Steering Committee members. The Chairperson provides leadership to the Committee by conducting the Steering Committee meetings and by interacting closely with the recipients during protocol development and implementation. The NIDDK Project Scientist may not serve as Chairperson. The NIDDK Program Official should be consulted regarding the selection of the Chairperson to provide any feedback regarding concerns regarding potential for bias or conflict of interest or lack of required expertise.

External Consultants

An independent panel of External Consultants may be established by the Steering Committee. The External Experts will review periodically interim progress of the UXXs and report to the Steering Committee members. Members of the panel of External Experts may be asked, on an ad hoc basis, to participate in the peer review of applications for new research initiatives that utilize special “opportunity pool” funds.

Dispute Resolution

Any disagreement that may arise on scientific/programmatic matters (within the scope of the award), between award recipients and the NIDDK may be brought to dispute resolution. A dispute resolution panel will be composed of three members --one selected by the recipient (or the Steering Committee, with the NIDDK member not voting), a second member selected by NIDD

S3R4ADSH44T S5MMAR$
AWARD N5MB4R: 5U01DK137272-02 REVISED

INSTIT5TION: UNIVERSITY OF COLORADO DENVER

Budget	Year 2
Salaries and Wages	$106,078
Fringe Benefits	$32,787
Personnel Costs (Subtotal)	$138,865
Other	$9,445
Subawards/Consortium/Contractual Costs	$502,231
TOTAL FEDERAL DC	$650,541

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

TOTAL FEDERAL F&A	$86,094
TOTAL COST	$736,635

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	56%
F&A Cost Base 1	$153,739
F&A Costs 1	$86,094

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/1/2025 12:05 AM

From: Bulls, Michelle G. (NIH/OD) [E]
To: spelton@sfsu.edu
Subject: Grant Termination Notification
Date: Wednesday, March 26, 2025 2:24:00 PM
Attachments: image001.jpg
image002.png

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 [6]

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.

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: sdsurfawards@sdsu.edu
Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 3:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/8/2025

Jennie Amison
San Diego State University
sdsurfawards@sdsu.edu

Dear Jennie Amison:

Effective with the date of this letter, funding for Project Number 5U54CA267789-04 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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: rvaldez3@unm.edu
Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 3:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/8/2025

Rebecca Valdez
University Of New Mexico
rvaldez3@unm.edu

Dear Rebecca Valdez:

Effective with the date of this letter, funding for Project Number 5U54CA272167-03 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]

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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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: dpaffrat@umaryland.edu
Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 3:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/8/2025

Dennis Paffrath
University Of Maryland Baltimore
dpaffrat@umaryland.edu

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

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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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: vchsgrants@health.ucsd.edu
Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 3:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/8/2025

Roxanne Knight
University Of California, San Diego
vchsgrants@health.ucsd.edu

Dear Roxanne Knight:

Effective with the date of this letter, funding for Project Number 5U54CA272220-03 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."

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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]

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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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: vchsgrants@health.ucsd.edu
Subject: Grant Termination Notification
Date: Tuesday, April 8, 2025 3:33:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

4/8/2025

Roxanne Knight
University Of California, San Diego
vchsgrants@health.ucsd.edu

Dear Roxanne Knight:

Effective with the date of this letter, funding for Project Number 5U54CA272220-03 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: SRA-PRE@fsu.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

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

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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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: nga@nyspi.columbia.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Greenhill, Janelle
New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc
nga@nyspi.columbia.edu

Dear Greenhill, Janelle:

Effective with the date of this letter, funding for Project Number 7R01MH129285-02 is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 3/15/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: research_admin@hphci.harvard.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:29:00 PM
Attachments: image002.png

National Institutes of Health
Office of Extramural Research

3/21/2025

Williams, Cary
Harvard Pilgrim Health Care, Inc.
research_admin@hphci.harvard.edu

Dear Williams, Cary:

Effective with the date of this letter, funding for Project Number 7R21DA058575-02 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 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)

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]
Subject: Award Revision Guidance and List of Terminated Grants via letter on 3/12
Date: Thursday, March 13, 2025 4:03:00 PM
Attachments: Termination Categories 3.13.25.docx
Terminated Grants 3-12_no subprojects.xlsx

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

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]
Subject: DEI Staff Guidance - Final - March 4 2025
Date: Tuesday, March 04, 2025 11:02:00 AM
Attachments: DEI Staff Guidance - Final 3.4.25.pdf

Good morning,
Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will that information out to all that were impacted by yesterday's termination list provided to us by HHS/ASA.
Thanks,
Michelle

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

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approved

Matt

Get Outlook for iOS

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

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]
Subject: DEI Staff Guidance - Final - March 4 2025
Date: Tuesday, March 04, 2025 11:02:00 AM
Attachments: DEI Staff Guidance - Final 3.4.25.pdf

Good morning,
Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will that information out to all that were impacted by yesterday's termination list provided to us by HHS/ASA.
Thanks,
Michelle

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.
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To: Bundesen, Liza (NIH/OD) [E]
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Date: Friday, February 28, 2025 2:54:19 PM

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Liza

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

Background

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

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February 10, 2025

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

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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
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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

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

March 24, 2025

Maria Reyes
California State University Long Beach
maria.reyes@csulb.edu

Dear Maria Reyes:

Funding for Project Number 5T34 GM49378-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on April 1, 2024 and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Matthew J. Memoli, M.D., M.S., Acting Director, NIH no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

From:	Bundesen, Liza (NIH/OD) [E]
To:	Bulls, Michelle G. (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]
Subject:	FW: Grants for immediate termination today
Date:	Friday, February 28, 2025 2:35:58 PM
Attachments:	28 FEB Grants for Cancellation.xlsx NIH Termination Letter 022625[42].docx

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From: Memoli, Matthew (NIH/OD) [E]
Sent: Friday, February 28, 2025 2:34 PM
To: Bundesen, Liza (NIH/OD) [E]
Cc: Smith, Brad M. EOP/DOGE ; Rachel.Riley@hhs.gov; Keveney, Sean (HHS/OGC)
Subject: Grants for immediate termination today

Liza,

Please terminate the grants on the attached spreadsheet by COB today. Attached is an OGC cleared termination letter.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED APRIL 2024-SEPTEMBER 2024 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[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.

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.].

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 [INSERT] 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 [the NIH Director or his designee] 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, [the NIH Director or his designee] 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,

---

[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).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

From: Lorsch, Jon (NIH/NIGMS) [E]
To: Bulls, Michelle G. (NIH/OD) [E]
Subject: FW: OER
Date: Monday, March 10, 2025 9:15:25 AM
Attachments: 1VH Termination 3-10-25.xlsx
Importance: High

Do you want to send this out or do you want me to? I assume it should go to GMAC with CC to EPMC?
Let me know how you would like to proceed.
Thanks.
Jon

From: "Memoli, Matthew (NIH/OD) [E]"
Date: Monday, March 10, 2025 at 8:37 AM
To: "Lorsch, Jon (NIH/NIGMS) [E]" , "Jacobson, Ray (NIH/CSR) [E]" , "Schwetz, Tara (NIH/OD) [E]"
Cc: "McElroy, James (NIH/OD) [E]" , "Burklow, John (NIH/OD) [E]" , "Lankford, David (NIH/OD) [E]"
Subject: OER

Good morning,
This is going to be a busy week for OER. There will be many actions this week similar to this. Two things this morning:

1. I would like an updated list of all grants terminated so far.
2. I attached al list of 43 grants, OTA, and NOFOs that need to be terminated/taken down, preferably by COB today if possible. These are on the first tab of the spreadsheet. These no longer align with HHS priorities so we can use the termination letters we have been using regarding HHS priorities.

Please have someone confirm with me when this is complete.
Thank you all again for your efforts and taking OER on.
Matt
--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Bulls, Michelle G. (NIH/OD) [E]
To: sharon.louie@ucsf.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Sharon Louie
University Of California, San Francisco
sharon.louie@ucsf.edu

Dear Sharon Louie:

Effective with the date of this letter, funding for Project Number 1R01HD112464-01A1 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 9/21/2024, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: GRANT-NOTICE@UWM.EDU
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

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, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: aabate@helunahealth.org
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Adam Abate
Public Health Foundation Enterprises
aabate@helunahealth.org

Dear Adam Abate:

Effective with the date of this letter, funding for Project Number 1R34MH132405-01 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 9/7/2023, 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."

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: anita.yip2@ucsf.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Yip, Anita
University Of California, San Francisco
anita.yip2@ucsf.edu

Dear Yip, Anita:

Effective with the date of this letter, funding for Project Number 3K12AR084219-26S1 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 9/16/2024, 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, on behalf of Erik Edgerton, Chief Grants Management Officer, NIAMS
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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: donne096@umn.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Patrick Donnell
University Of Minnesota
donne096@umn.edu

Dear Patrick Donnell:

Effective with the date of this letter, funding for Project Number 3R01AG075734-03S1 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 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12]

12 *Id.* § 50.406(b)

From: Bulls, Michelle G. (NIH/OD) [E]
To: ADENSON@UMASS.EDU
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

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, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: mspiva@uci.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Maria G. Diaz
University Of California-Irvine
mspiva@uci.edu

Dear Maria G. Diaz:

Effective with the date of this letter, funding for Project Number 5DP2AI164315-04 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 9/1/2023, 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."

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: Shannon.Schechter@ucsf.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Shannon P Schechter
University Of California, San Francisco
Shannon.Schechter@ucsf.edu

Dear Shannon P Schechter:

Effective with the date of this letter, funding for Project Number 5F31AA030722-02 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

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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: dboone14@umd.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Danette Boone
Univ Of Maryland, College Park
dboone14@umd.edu

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, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: sponsoredprojects@uoregon.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Business Official
University Of Oregon
sponsoredprojects@uoregon.edu

Dear Business Official:

Effective with the date of this letter, funding for Project Number 5K08MD019314-03 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 2/1/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: crschulz@wisc.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Schulz, Christy R
University Of Wisconsin-Madison
crschulz@wisc.edu

Dear Schulz, Christy R:

Effective with the date of this letter, funding for Project Number 5P01HD109850-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the

Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: schumacb@uwm.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Brooke Gilbertson
University Of Wisconsin Milwaukee
schumacb@uwm.edu

Dear Brooke Gilbertson:

Effective with the date of this letter, funding for Project Number 5R01AA027248-05 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 6/1/2023, 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."

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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: grants-office@columbia.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:27:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Odeh-Ramadan, Rudina
Columbia University Health Sciences
grants-office@columbia.edu

Dear Odeh-Ramadan, Rudina:

Effective with the date of this letter, funding for Project Number 5R01AA027252-05 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 7/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: alodojew@buffalo.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: gcat3@yale.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Ms. Varick, Tina
Yale University
gcat3@yale.edu

Dear Ms. Varick, Tina:

Effective with the date of this letter, funding for Project Number 5R01AA029088-03 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, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: minerj@uwm.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Jeremy Miner
University Of Wisconsin Milwaukee
minerj@uwm.edu

Dear Jeremy Miner:

Effective with the date of this letter, funding for Project Number 5R01AA031213-02 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 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: vtroxler@umn.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Victoria Troxler
University Of Minnesota
vtroxler@umn.edu

Dear Victoria Troxler:

Effective with the date of this letter, funding for Project Number 5R01AG060944-05 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 6/1/2023, 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."

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 Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12]

12 *Id.* § 50.406(b)

From: Bulls, Michelle G. (NIH/OD) [E]
To: jill.tuley@unlv.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:33:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Tuley, Jill
University Of Nevada Las Vegas
jill.tuley@unlv.edu

Dear Tuley, Jill:

Effective with the date of this letter, funding for Project Number 5R01AG083177-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 5/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12]

12 *Id.* § 50.406(b)

From: Bulls, Michelle G. (NIH/OD) [E]
To: phokanson@pire.org
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Patricia Susan Hokanson
Pacific Institute For Res And Evaluation
phokanson@pire.org

Dear Patricia Susan Hokanson:

Effective with the date of this letter, funding for Project Number 5R01NR021019-03 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 2/1/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2025 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Brian Albertini, Chief Grants Management Officer, NINR
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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: pdale@phfe.org
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Peter David Dale
Public Health Foundation Enterprises
pdale@phfe.org

Dear Peter David Dale:

Effective with the date of this letter, funding for Project Number 5R25MH119858-05 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 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]

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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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: research.funding@umassmed.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: ALEX.FRANZ@CUANSCHUTZ.EDU
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

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

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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: steve.torok@sdsu.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

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, 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: chlaawards@chla.usc.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Lilit Amirkhanyan
Children'S Hospital Of Los Angeles
chlaawards@chla.usc.edu

Dear Lilit Amirkhanyan:

Effective with the date of this letter, funding for Project Number 5U01DA036926-10 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 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)

From: Bulls, Michelle G. (NIH/OD) [E]
To: nga@nyspi.columbia.edu
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:34:00 PM
Attachments: image001.jpg
image002.png

3/21/2025

Greenhill, Janelle
New York State Psychiatric Institute Dba Research Foundation For Mental Hygiene, Inc
nga@nyspi.columbia.edu

Dear Greenhill, Janelle:

Effective with the date of this letter, funding for Project Number 7R01MH129285-02 is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 3/15/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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 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)

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Smith, Brad M. EOP/DOGE; Rachel.Riley@hhs.gov; Keveney, Sean (HHS/OGC)
Subject: Grants for immediate termination today
Date: Friday, February 28, 2025 2:35:29 PM
Attachments: 28 FEB Grants for Cancellation.xlsx
NIH Termination Letter 022625[42].docx

Liza,

Please terminate the grants on the attached spreadsheet by COB today. Attached is an OGC cleared termination letter.

Thank you,
Matt

--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED APRIL 2024-SEPTEMBER 2024 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[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.

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.].

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 [INSERT] 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 [the NIH Director or his designee] 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, [the NIH Director or his designee] 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,

---

[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).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024 (TO BE DELTED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement,[13] and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination.[14]

The 2022 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[15]

The 2022 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."[16] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[17] 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[13] https://grants.nih.gov/grants/policy/nihgps/nihgps_2022.pdf.
[14] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[15] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[16] 2022 Policy Statement at IIA-1.
[17] *Id.* at IIA-153.

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.].

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,"[18] no corrective action is possible here. The premise of Project Number [INSERT] 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.[19] 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*.[20]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[21] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[22]

You must submit a request for such review to [the NIH Director or his designee] 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, [the NIH Director or his designee] may grant an extension of time.[23]

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.[24]

Sincerely,

---

[18] 2022 Policy Statement at IIA-154.
[19] *See* 2 C.F.R. § 200.343 (2023).
[20] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[21] *See* 45 C.F.R. § 75.374.
[22] See 42 C.F.R. Part 50, Subpart D.
[23] *Id.* § 50.406(a).
[24] *Id.* § 50.406(b).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

[insert sig block]

From: Lorsch, Jon (NIH/NIGMS) [E]
To: Bulls, Michelle G. (NIH/OD) [E]
Cc: Ta, Kristin (NIH/OD) [E]
Subject: Grants for termination (red) and renegotiation (yellow)
Date: Monday, March 31, 2025 8:30:19 AM
Attachments: Influencing Opinions Grants.xlsx

Michelle,
Per MM, the grants highlighted in red in the attached should be terminated because they do not effectuate NIH/HHS' priorities, specifically as they relate to vaccine hesitancy and/or attempts to influence public opinions. The two grants in yellow should be renegotiated by the IC (if possible), as described below and in column U of the spreadsheet.
Please let me know if there are any questions.
Many thanks.
Jon

From: "Memoli, Matthew (NIH/OD) [E]"
Date: Friday, March 28, 2025 at 4:27 PM
To: "Lorsch, Jon (NIH/NIGMS) [E]"
Subject: Grants
Hi Jon,
After talking with OGC, the ones in red we should terminate. The ones in green should not be touched. The ones in yellow I would like to negotiate. One it would be great if they just changed the name to what they are doing which is researching smoking cessation. The 4corners one it would be great if they just got rid of the HPV vaccine hesitancy piece. It would be great if we could get them to agree and keep it in place. The other blue ones I am going to think about some more, we may want to suspend them and then see. Let's handle red, green, and yellow first.
Matt
--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]; Bulls, Michelle G. (NIH/OD) [E]
Subject: Grants for termination
Date: Monday, March 24, 2025 10:23:10 AM
Attachments: Memorandum - Covid-19 Termination.pdf
For termination 3-24.xlsx

Good morning,

We have been asked to terminate the list of approximately 120 grants by COB today. The memo from HHS OGC defines the reason for the termination so our letter should mirror this memo. Attached Is an excel sheet with the grants for termination. These have already been reviewed, so please terminate them all.

Thanks,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]; Bulls, Michelle G. (NIH/OD) [E]
Subject: Grants for termination
Date: Wednesday, March 26, 2025 11:04:30 AM

Good morning,

These 4 NIEHS grants need to be terminated due to NIH/HHS priorities ASAP

- **Examining Anti-Racist Healing in Nature to Protect Telomeres of Transitional Age BIPOC for Health Equity.**
  - https://reporter.nih.gov/search/yaadS0Oi-UO9YW5xrsZ9gg/projects/charts/project-details/11100878
- **Society of Toxicology Undergraduate** Diversity **Program**
  - https://reporter.nih.gov/search/yaadS0Oi-UO9YW5xrsZ9gg/projects/charts/project-details/11023087

These 2 may be able to be negotiated to remove some problematic things, but if not then need to be terminated

- **An assessment of environmental and neighborhood-level risk factors for subfertility among Black women in the U.S.**
  - https://reporter.nih.gov/search/CmaReC1BZUatzRq62UbVcg/projects/charts/project-details/11252912
- **Disentangling the role of culture, life stage, and information design to facilitate** equity **in data report back**
  - https://reporter.nih.gov/search/CmaReC1BZUatzRq62UbVcg/projects/charts/project-details/10867569

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary

The General Counsel
Washington, D.C. 20201

MEMORANDUM

TO: Matthew Memoli, Director of NIH
Susan Monarez, PHD, Acting Director of CDC
Christopher D. Carroll, Principal Deputy Assistant Secretary, SAMHSA
Andrew Gradison, Acting Assistant Secretary, ACF

FROM: Sean R. Keveney, Acting General Counsel

DATE: March 20, 2025

SUBJECT: Termination of COVID-19 Grants

During the COVID-19 pandemic, the Department of Health and Human Services (HHS) administered several pandemic-related grant programs. But the pandemic is over.[1] HHS regulations permit grant termination "if the non-Federal entity fails to comply with the terms and conditions of the award," or, separately, "for cause."[2] The regulations do not define "for cause." When regulations do not provide a definition, the ordinary meaning of a word or phrase governs.[3] Dictionaries define "cause" as "a ground for legal action."[4] Actions taken "for cause" are "distinguished from decisions or actions considered to be arbitrary or capricious."[5] And "[t]he circumstances under which cause … exists are determined on a case by case basis."[6]

The end of the pandemic provides cause to terminate COVID-related grants. These grants were issued for a limited purpose: To ameliorate the effects of the pandemic.[7] Now that the pandemic is over, the grants are no longer necessary. It is not arbitrary or capricious to terminate limited-purpose grants when their purpose has run out.

Thank you for your prompt attention to this matter.

---

[1] *See* Pub. L. 118-3, 137 Stat. 6, 6 (Apr. 10, 2023).
[2] 45 C.F.R. 75.372(a)(1)-(2).
[3] *Zhang v. U.S. Citizenship & Immig. Servs.*, 978 F.3d 1314, 1319 (D.C. Cir. 2020); *accord Kisor v. Wilkie*, 588 U.S. 558, 573 (2019) (requiring courts to apply "all the standard tools of interpretation" to regulations).
[4] *Cause*, *Black's Law Dictionary* (12th ed. 2024); *accord Cause*, *West's Encyclopedia of American Law* (2d ed. 2005) ("[A] ground of a legal action."); *Just Cause*, *Merriam-Webster's Dictionary of Law* (2016) ("[C]ause that a person ordinary intelligence would consider a fair and reasonable justification for an act.").
[5] *Cause*, *West's Encyclopedia of American Law* (2d ed. 2005)
[6] *Cause*, *Merriam-Webster's Dictionary of Law* (2016).
[7] *See* attached list of grants to be terminated.

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]; Johnson, Alfred (NIH/OD) [E]; Schor, Nina (NIH/OD) [E]
Subject: Memo on NIH priorities
Date: Friday, February 21, 2025 2:54:40 PM
Attachments: 2695_001.pdf

Hello,

After working with OGC we determined it was possible to set priorities at an NIH level, which now allows us to proceed with the process of making sure our programs are meeting these goals. I will talk with you individually about the plan of action.

Thanks,
Matt

--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

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, 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.

Likewise, 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 either.

For these reasons and pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371–373),[1] the Director of NIH hereby directs:

> NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025

Matthew J. Memoli, M.D.
Acting Director of NIH

[1] To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

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 *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 23:37:45 -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)

Fringe Benefits	$39,922
Personnel Costs (Subtotal)	$181,494
Travel	$22,500
Other	$134
Subawards/Consortium/Contractual Costs	$275,324
Publication Costs	$851
Federal Direct Costs	$480,303
Federal F&A Costs	$127,087
Approved Budget	$607,390
Total Amount of Federal Funds Authorized (Federal Share)	$607,390
TOTAL FEDERAL AWARD AMOUNT	$607,390
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$607,390	$607,390

Fiscal Information:
Payment System Identifier: 1135598093A7
Document Number: RMH118004A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
MH	8472592	$607,390

NIH Administrative Data:
PCC: 9A-ASGP / **OC**: 41025 / **Released**: 03/12/2025
Award Processed: 03/13/2025 12:01:33 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MH118004-05 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 – 5R01MH118004-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-

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Department of Health and Human Services
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Notice of Award
EAI6F D01Mu13B335
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
TuIT LhAhU S6 IVUDLIhKYhu U
19#0 RU6 6 K D7
CTOSM, SLYTu 43210

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
131#0259B#A1

4. Employer Identification Number (EIN)
31#0259B#

5. Data Universal Numbering System (DUNS)
B32128323

6. Recipient's Unique Entity Identifier
7OW, LOWAJWD1

7. Project Director or Principal Investigator
Cu DILhI6 A 7KADYPu 7 jContabt(
Assistant Professor
dcar)13@osl)edl
#14-#BB-0#23

8. Authorized Official
LtemHanie , o. an
zo. an)1B@osl)edl

Federal Agency Information

9. Awarding Agency Contact Information
Oal ren 6 iboNe Cl . . ings
Grants Manage. ent LmebiaNst
6 AhIT6 AOI6 LhIhShU TE MU6 hAO
u UAOhu
Nal ren)bl . . ings@niH)gox

10. Program Official Contact Information
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6 AhIT6 AOI6 LhIhShU TE MU6 hAO
u UAOhu
erib). I rmHc@niH)gox
j301(443-9230

Federal Award Information

11. Award Number
1D01Mu13B335-01

12. Unique Federal Award Identification Number (FAIN)
D01Mu13B335

13. Statutory Authority
42 SLC 241 42 CED 52

14. Federal Award Project Title
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15. Assistance Listing Number
93)242

16. Assistance Listing Program Title
MentaNu eaNH DesearbH Grants

17. Award Action Type
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18. Is the Award R&D?
Kes

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) 7irebt Cost A. ol nt	" 0
20 z) Indirebt Cost A. ol nt	" 0
21. Al tHoriked Carrcoxer	
22. Tffset	
23. hotaNA. ol nt of EederaNEl nds TzNgated tHis zI dget meriod	" B15YBB1
24. Total Approved Cost Sharing or Matching, where applicable	" 0
25. Total Federal and Non-Federal Approved this Budget Period	" B15YBB1
26. Project Period Start Date 01/01/2025 **– End Date** 03/20/2025	
27. hotaNA. ol nt of tHe EederaNA$ ard inbNding Ammroxed Cost LHaring or MatbHing tHis Prowebt Period	" B15YBB1

28. Authorized Treatment of Program Income
AdditionaNCosts

29. Grants Management Officer - Signature
hHeresa D) Jarosiy

30. Remarks
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SECTION I – AWARD DATA – 1R01MH138335-01 REVISED

Principal Investigator(s):
Cu DlLhl6 A 7KAD jbontabt(YPu 7
, rian EeinsteinYPu 7

Award e-mailed to: 6 lu a$ ard@osl)edl

7 ear Al tHoriked TffibiaN

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)
Salaries and Wages " 200Y422

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Fringe Benefits	" ##YB8#
Personnel Costs (Subtotal)	" 2#8Y29B
Materials & Supplies	" 5Y400
Travel	" 5Y000
Other	" ##Y000
Subawards/Consortium/Contractual Costs	" 231Y432
Federal Direct Costs	" 585Y130
Federal F&A Costs	" 240Y851
Approved Budget	" B15YBB1
Total Amount of Federal Funds Authorized (Federal Share)	" B15YBB1
TOTAL FEDERAL AWARD AMOUNT	" B15YBB1
AMOUNT OF THIS ACTION (FEDERAL SHARE)	" 0

SUMMARY TOTALS FOR ALL YEARS jfor tHis 7obl . ent 6l . zer(		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	" B15YBB1	" B15YBB1

Fiscal Information:

Payment System Identifier:	131#0259B#A1
Document Number:	DMu13B335A
PMS Account Type:	PjLIzabboInt(
Fiscal Year:	2025

IC	CA6	2025
Mu	B022585	" B15YBB1

NIH Administrative Data:
PCC: , 4-h, 7 / **OC**: 41021 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:10:33 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MH138335-01 REVISED

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SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MH138335-01 REVISED

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SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R01MH138335-01 REVISED

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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

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

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

From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]
Cc: Cutler, Diane (HHS/IOS); Smith, Brad M. EOP/DOGE; Bulls, Michelle G. (NIH/OD) [E]
Subject: New list for termination
Date: Thursday, March 13, 2025 9:03:01 AM
Attachments: Grants for Termination 3-13 to 3-24-25.xlsx

Jon,

Here is an additional list of grants for termination There are 530 grants here. I do not expect these to get done today. Please complete these by COB next Friday if possible. A daily evening update on how many were terminated would be appreciated. I want to thank you and Michelle for your diligent work getting this done. Michelle has been doing a lot of heavy lifting and it has not gone unnoticed.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024

March 3, 2025

Ms. Anastasia Hendry
Grant Analyst
9500 Gilman Drive
La Jolla, CA 920930041

Ms. Anastasia Hendry:

Funding for Project Number 5R01HD111650-02 is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination.[2]

The 2022 Policy Statement applies to your project because NIH approved your grant on December 12, 2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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.

- 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.].

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps_2022.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] 2022 Policy Statement at IIA-1.
[5] *Id.* at IIA-153.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

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 5R01HD111650-02 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 *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 NIH Acting Director, Dr. Matthew J. Memoli or his designee 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, NIH Director, Dr. Matthew J. Memoli or his designee 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,

Maggie Young

Chief, Grants Management Officer

[6] 2022 Policy Statement at IIA-154.
[7] *See* 2 C.F.R. § 200.343 (2023).
[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).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

Dr. Ronna Popkin
4800 Sand Point Way NE
Seattle Children's Hospital
Seattle, WA

Dr. Popkin:

Funding for Project Number 5R21HD107311-02 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 September 1, 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. 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.

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 5R21HD107311-02 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. Matthew Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Matthew 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,

[insert sig block]

[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).

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2022-MARCH 2024 (TO BE DELTED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2022 National Institutes of Health ("NIH") Grants Policy Statement,[13] and 2 C.F.R. § 200.340(a)(2) (2023). This letter constitutes a notice of termination.[14]

The 2022 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[15]

The 2022 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."[16] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[17] 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[13] https://grants.nih.gov/grants/policy/nihgps/nihgps_2022.pdf.
[14] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[15] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[16] 2022 Policy Statement at IIA-1.
[17] *Id.* at IIA-153.

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.].

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,"[18] no corrective action is possible here. The premise of Project Number [INSERT] 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.[19] 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*.[20]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[21] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[22]

You must submit a request for such review to [the NIH Director or his designee] 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, [the NIH Director or his designee] may grant an extension of time.[23]

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.[24]

Sincerely,

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[18] 2022 Policy Statement at IIA-154.
[19] *See* 2 C.F.R. § 200.343 (2023).
[20] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[21] *See* 45 C.F.R. § 75.374.
[22] See 42 C.F.R. Part 50, Subpart D.
[23] *Id.* § 50.406(a).
[24] *Id.* § 50.406(b).

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[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

FOR GRANTS ISSUED DECEMBER 2021-NOVEMBER 2022 (TO BE DELETED)

[Address block & date]

[Grant recipient]:

Funding for Project Number [INSERT] is hereby terminated pursuant to the 2021 National Institutes of Health ("NIH") Grants Policy Statement,[25] and 2 C.F.R. § 200.340(a)(2) (2022). This letter constitutes a notice of termination.[26]

The 2021 Policy Statement applies to your project because NIH approved your grant on [INSERT DATE], and "obligations generally should be determined by reference to the law in effect when the grants were made."[27]

The 2021 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."[28] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[29] 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. [INSERT EXPLANATION—EXAMPLES BELOW

- 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

[25] https://grants.nih.gov/grants/policy/nihgps/nihgps_2021.pdf.
[26] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[27] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[28] 2022 Policy Statement at IIA-1.
[29] *Id.* at IIA-152.

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.].

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,"[30] no corrective action is possible here. The premise of Project Number [INSERT] 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.[31] 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*.[32]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[33] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[34]

You must submit a request for such review to [the NIH Director or his designee] 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, [the NIH Director or his designee] may grant an extension of time.[35]

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.[36]

Sincerely,

---

[30] 2021 Policy Statement at IIA-154.
[31] *See* 2 C.F.R. § 200.343 (2022).
[32] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[33] *See* 45 C.F.R. § 75.374.
[34] See 42 C.F.R. Part 50, Subpart D.
[35] *Id.* § 50.406(a).
[36] *Id.* § 50.406(b).

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[insert sig block]

PRIVILEGED, CONFIDENTIAL, PRE-DECISIONAL

National Institute on Aging
Bethesda, MD 20892

Stephanie Page
University of Nevada, Las Vegas
4505 S. Maryland Parkway
Las Vegas, NV 89154

Dear Ms. Page,

Funding for Project Number 5K01AG056669-05 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 07/15/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. 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.

- 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.

[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 Project Number 5K01AG056669-05 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 NIH Acting Director, Matthew J. Memoli, M.D., M.S., 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, NIH Acting Director, Matthew J. Memoli, M.D., M.S., 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,

[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).

From: Bulls, Michelle (NIH/OD) [E]
To: Riley, Rachel (OS/ASA)
Cc: Bulls, Michelle (NIH/OD) [E]
Subject: NIH Vaccine Hesitancy (VH) Termination Letter Clean_
Date: Tuesday, March 11, 2025 9:10:00 PM
Attachments: NIH Vaccine Hesitancy (VH) Termination Letter Clean .docx

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Modified the letter to allow folks to fill in the correct GPS terms. I think it's safe to put in 2023 for all, and we will correct it in the term once we issue the award to revise and update it.
Thanks,
Michelle

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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

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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

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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 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

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[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.] 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICs do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

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Category 2B:

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.

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- OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICs.

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

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

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

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

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

Category 5: Awards to Entities in certain foreign countries

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

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- Office of Foreign Assets Control Sanctions List

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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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

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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 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.
- 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.

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Appendix 4 - 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

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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

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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.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards, when termination letter is issued.

Recipients are required to request approval from OPERA before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare. These are the only approvals that will be issued. OPERA will work with the IC to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS.

Recipients are required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award**.**

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type NIH OD

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

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Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Impacts on the Biomedical Workforce:

- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: **Type** **NIH** **OD**

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award**.**

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

  [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type
OD NIH

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Impacts on the Biomedical Workforce:

- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  > NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.
  >
  > Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  > **Term of Award:** The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type NIH OD

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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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

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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

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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 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

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[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.] 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICs do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

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Category 2B:

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.

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- OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICs.

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

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

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

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

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

Category 5: Awards to Entities in certain foreign countries

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

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- Office of Foreign Assets Control Sanctions List

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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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, M.D., Acting Secretary

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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 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.
- 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.

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Appendix 4 - 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

Get Outlook for iOS

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

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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.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards, when termination letter is issued.

Recipients are required to request approval from OPERA before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare. These are the only approvals that will be issued. OPERA will work with the IC to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS.

Recipients are required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

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From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]; Bhattacharya, Jayanta (NIH/OD) [E]
Subject: Re: Additional Influencing Public Opinion Grants
Date: Friday, May 09, 2025 10:03:01 AM

Thanks Jon,
Please terminate those grants for being inconsistent with agency priorities.
Matt
--
Matthew J. Memoli, MD, MS
Principal Deputy Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Lorsch, Jon (NIH/NIGMS) [E]
Date: Friday, May 9, 2025 at 10:01 AM
To: Memoli, Matthew (NIH/OD) [E]
Cc: Bulls, Michelle G. (NIH/OD) [E]
Subject: Additional Influencing Public Opinion Grants

Matt,
As discussed, here are several additional grants that appear to focus on studies aimed at influencing public opinion. Please let us know how you would like to proceed.
Many thanks.
Jon

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Bulls, Michelle (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Sass-Hurst, Brian (NIH/OD) [E]; Whatley, Alan (NIH/OD) [E]
Subject: RE: DEI Staff Guidance - Final - March 4 2025
Date: Tuesday, March 04, 2025 2:08:00 PM
Attachments: DEI Staff Guidance - Final - March 4 2025.pdf

Hi,
Updated to add watermark, not for distribution label, and to provide clarity on deobligating the funds after termination letters are submitted.
For CGMOs that issued termination letters yesterday (and Friday, if you still need to revise your awards) – please review Appendix 2 – Guidance for staff to use when terminating awards identified by HHS or the IC related to DEI and let me know if you need any additional information. If not, please proceed with revising the awards that you sent termination letters for using the attached guidance. Please let me know when the awards have been issued. I appreciate your time and sorry for so many emails on this just trying to make sure we get this right. Let me know if you have any questions and we will discuss tomorrow.
Thanks,
Michelle

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Tuesday, March 4, 2025 11:02 AM
To: Chief GMOs
Cc: Bulls, Michelle G. (NIH/OD) [E] ; Ta, Kristin (NIH/OD) [E] ; Sass-Hurst, Brian (NIH/OD) [E]
Subject: DEI Staff Guidance - Final - March 4 2025

Good morning,
Attached is staff guidance that includes the DEI term along with details on when the term must be applied. Let's plan to talk through this guidance and note Dr. Memoli has **approved** the DEI term for immediate use. I have also added the process for terminating awards based in DEI as provided to us by HHS. I will follow up with a few of you to pull out the details needed to address terminations that were made yesterday—just to pull the information out and to address specific questions. Finishing up meetings and then, I will send the specific details from the attached document to the ICs that were impacted by yesterday's termination list provided to us by HHS/ASA. [my apologies for sending this in the middle of a meeting, and missing words! This email was edited to provide clarity]
Thanks,
Michelle

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NIH Grants Management 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.

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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.

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From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]; Lankford, David (NIH/OD) [E]
Subject: Re: One more thought...
Date: Monday, March 10, 2025 1:15:45 PM
Attachments: NIH Termination Letter_Columbia (2024 Statement)_v3 (signed).docx
Columbia Grants for Suspension or Termination.xlsx

Jon,

Attached is a termination letter that was drafted. I think the last paragraph is the relevant part we may need to use, but I defer to David and OGC.

David, we would like to send a single letter to the University telling them we intend to terminate the grants listed in the attached spreadsheet. We will the proceed with orderly terminations through our normal process.

We would like an approved letter sent by close of business today.

Thanks,
Matt

--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Lorsch, Jon (NIH/NIGMS) [E] <jon.lorsch@nih.gov>
Date: Monday, March 10, 2025 at 1:03 PM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Subject: One more thought...

What if we issued a letter to the VPR at the university saying we “intend to terminate the following awards...” with a list of the awards. That would make the point and then we could follow an orderly procedure for doing it. Perhaps there would be a resolution before that process finished?

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

March 7, 2025

President Katrina Armstrong
The Trustees of Columbia University in the City of New York
202 Low Library
535 W. 116 St.
New York, NY 10027

Dear President Armstrong:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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.

NIH is responsible for ensuring that its limited resources are appropriately allocated. NIH policy is that grant dollars should support institutions that foster safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry—and should not subsidize institutions that are not built on American values of free speech, mutual respect, and open debate.[6] In this vein, NIH is aware of recent events at Columbia University involving antisemitic action that suggest the institution has a disturbing lack of concern for the safety and wellbeing of Jewish students. Columbia's ongoing inaction in the face of repeated and severe harassment and targeting of Jewish students has ground day-to-day campus operations to a halt, deprived Jewish students of learning and research opportunities to which they are entitled, and brought shame upon the University and our nation as a whole. Supporting research in such an

[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, Section 4.

environment is plainly inconsistent with NIH's priorities and raison d'etre of funding and championing the very best American research and educational institutions.

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,"[7] no corrective action is possible here. The premise of Project Number [INSERT] 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.[8] 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*.[9]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[10] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[11]

You must submit a request for such review to Director 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.[12]

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.[13]

Sincerely,

Matthew J. Memoli, M.D., M.S.
Acting Director, NIH

[7] 2024 Policy Statement at IIA-156.
[8] *See* 2 C.F.R. § 200.343 (2024).
[9] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[10] *See* 45 C.F.R. § 75.374.
[11] See 42 C.F.R. Part 50, Subpart D.
[12] *Id.* § 50.406(a).
[13] *Id.* § 50.406(b).

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

[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).

From: Riley, Rachel (OS/ASA)
To: Bulls, Michelle G. (NIH/OD) [E]; Memoli, Matthew (NIH/OD) [E]
Subject: Shortlist of SGM for Tonight
Date: Tuesday, March 11, 2025 9:43:08 PM
Attachments: NIH Grants 031125.xlsx

Dr. Memoli –
Please see a short list below/attached; I have sent you 6 in case you find an issue with any one. If you are comfortable, the wonderful @Bulls, Michelle G. (NIH/OD) [E] will work to action tonight:
I will then get you an updated combined list for tomorrow!
Thanks,
Rachel

From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: EPMC Principals; Curling, Mitchell (NIH/NIDDK) [E]
Subject: Staff Guidance - Updates Made during GMAC - 5/12
Date: Thursday, May 15, 2025 9:57:00 AM
Attachments: NIH Grants Management Staff Guidance - Alignment with Priorities - Draft - 5.12.2025 Updates.pdf

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5/15: New Updates from those below:

- NCE section - addressed second and beyond.
- ICO reconsideration section – removed the CGMO as POC and replaced w/IC Director.

5/7: Updated staff guidance based on discussions…

- Emphasize that whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.
- Updated term language to note that requests for ICO reconsiderations should be sent to the IC Director.
- Updated Category 2 when ICOs are unable to remove activities that are not an NIH/HHS priority. ICOs do not need to work with OPERA on the bilateral termination, rather, OPERA must be notified, for tracking purposes.
- Updated Category 2B. Noted that ICOs should document any changes to the title or abstract in the grant file.
- Category 2:
  - Added term for bilateral terminations.
  - Clarified that for unilateral terminations, the ICO must issue a letter as outlined in Termination Type 3 – ICO determinations
- Category 4: Added a note referencing NOT-oD-25-104. At this time, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities that include a subaward to a foreign entity.
- Appendix 8: Updated template letter, to be used for ICO determinations, to reflect ICO reconsideration language and IC CGMO as signatory.
- Added FAQ on negotiating with conference grant recipients to remove DEI sessions or activities.

Reminder – we will finalize once we receive the memo from the Director.

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For all NCE requests, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award**.**

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type NIH OD

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

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Impacts on the Biomedical Workforce:

- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. **Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.**

    The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. **If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?**

    No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. **For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?**

    Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. **For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?**

    Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. **If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?**

    No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. **If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?**

    Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. **For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.**

    In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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From: Bulls, Michelle (NIH/OD) [E]
To: Chief GMOs
Cc: Perry Jones, Aretina (NIH/NIDDK) [E]; Rosenberg, Mary (NIH/NIDDK) [E]; Curling, Mitchell (NIH/NIDDK) [E]
Subject: Staff Guidance - Updates Made during GMAC
Date: Wednesday, May 07, 2025 4:04:00 PM
Attachments: NIH Grants Management Staff Guidance - Alignment with Priorities - Draft - 5.7.2025 Updates.pdf

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Updated staff guidance based on discussions…

- Emphasize that whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.
- Updated term language to note that requests for ICO reconsiderations should be sent to the IC Director.
- Updated Category 2 when ICOs are unable to remove activities that are not an NIH/HHS priority. ICOs do not need to work with OPERA on the bilateral termination, rather, OPERA must be notified, for tracking purposes.
- Updated Category 2B. Noted that ICOs should document any changes to the title or abstract in the grant file.
- Category 2:
    - Added term for bilateral terminations.
    - Clarified that for unilateral terminations, the ICO must issue a letter as outlined in Termination Type 3 – ICO determinations
- Category 4: Added a note referencing NOT-oD-25-104. At this time, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities that include a subaward to a foreign entity.
- Appendix 8: Updated template letter, to be used for ICO determinations, to reflect ICO reconsideration language and IC CGMO as signatory.
- Added FAQ on negotiating with conference grant recipients to remove DEI sessions or activities.

Reminder – we will finalize once we receive the memo from the Director.

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NIH Grants Management Staff Guidance – Award Assessments for Alignment with Agency Priorities – DRAFT

Final Issue Date: Pending NIH Director's updated priorities

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). This guidance seeks to expand the scope of the categories within to include other agency priorities that will be defined by the Director, NIH. The Director will issue a guide notice to publicize the agency's updated priorities in an effort to be transparent as research priorities shift.

NOFO Guidance

NIH is required to submit forecast reports to HHS prior to issuing new or reissued Notices of Funding Opportunities (NOFO's) within the NIH Guide for Grants and Contracts and Grants.gov. See Appendix 5 for the workflow.

Award Guidance

Prior to issuing all awards (competing and non-competing, monetary and non-monetary (e.g., carryover requests, no-cost extensions, etc.)), ICO's must review the specific aims/major goals of the project to assess whether the proposed project contains any DEI and/or other research activities that are not an NIH/HHS priority/authority. To avoid issuing awards, in error, that support these activities ICO's must take care to completely excise all non-priority activities using the following categories.

ICO's should review the current application/RPPR under consideration, only. ICO's should not request retroactive changes to previous RPPRs and competitive applications to modify language related to research that has already been conducted.

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, etc. after the priorities memo is issued), 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. Whether the NOFO was unpublished or expired naturally, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award.

This applies to all projects, including phased awards, etc. Reminder: CGMOs requested access to the NOFO list, and NIH leadership provided the following interim process: CGMOs must consult with their Division of Extramural Activities (DEA) rep to obtain up to date information on NOFOs.

- **Action:** ICO's must not issue the award (competing or non-competing).

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- For ongoing projects where NIH will not issue the next Type 5 (ICO determination not HHS list), the ICO must:
  - Issue a revised award to end the award at the end of the current budget period and remove all outyears. A termination letter is not required.
  - Add the action to the master spreadsheet located at: OD OPERA Grant Action Tracking (Access limited to CGMOs. CGMOs may email OPERA leadership to identify a delegate, if needed).
  - Include the following term in the revised NOA:

    Term of Award:

    Effective with this Notice of Award, this project is terminated. [Insert appropriate category from Appendix 3, verbatim]. Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

    This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- In this instance, there is no hard funds restriction required. The recipient will submit their Final FFR in accordance with the term and conditions, and any remaining funding will be deobligated by the FFR-C upon review and acceptance of the FFR.
- NOTE: OPERA recognizes that the closeout letters will be automatically sent, so we are working internally with the closeout support center staff to manage this process. If you receive inquiries, please point the inquirer to: OPERALeadership@nih.gov
- **No cost extension requests:** For second and third NCE's, ICO's must determine if the sole purpose of the grant was to support research activities that are no longer an NIH/HHS

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priority/authority and, if so, issue an award to immediately 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, ICO staff must still determine if non-NIH/HHS priority/authority activities are proposed during the extension period. Extensions may only be approved for orderly phaseout, and funds may not be used to support any non-NIH/HHS priority/authority research activities.

- ICO's 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 an orderly phaseout of the project, no other reasons are allowed. NIH grants funds must not be used to support [insert category – e.g., Diversity, Equity and Inclusion (DEI), COVID 19, 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 phaseout 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 (see Action 2) 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).

- Note: Activities required to comply with NIH inclusion policies are not considered DEI activities.
- **Action 1:** Funding ICO 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.
  - After an informal conversation, the ICO must send a written request to the AOR outlining what portion of the aims and budget must be modified to document the renegotiation process:
    - 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, or other non-HHS/NIH priorities, or countries of concern]. [Funding IC] has identified [insert appropriate activity taken from the list above] activities within section

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[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.

- Once the recipient responds and the ICO and the recipient agree to the changes, the ICO must direct the AOR to submit a revised face page, specific aims and budget via the prior approval module 'Other Request' type. See eRA online help for instructions.
- Once the ICO renegotiates the revised specific aims, the ICO must upload into the Additions for GM section of the grant folder the new aims. These must be uploaded under the file group "Award Documents: Revised Aims and Abstract".
- If the ICO renegotiates a revised budget, the ICO should update the GM workbook, as appropriate.

- **Action 2:** Once the ICO and the applicant/recipient have reached an agreement, and updated documents are received and properly filed as outlined above, 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, vaccine hesitancy, climate change, 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.

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- **Unable to remove activities that are not an NIH/HHS priority:** If the ICO and the applicant/recipient cannot reach an agreement, or the project is no longer viable without the non-compliant activities, the ICO cannot proceed with the award. For ongoing projects, the ICO must notify OPERA (OPERAleadership@nih.gov) and negotiate a bilateral termination of the project. For bilateral terminations, the ICO must Issue a revised award to remove all outyears and include the following term in Section IV of the NOA.

  NIH is bilaterally terminating this award effective [effective date] in accordance with the request dated [date], because the project does not align with NIH priorities. No additional funding will be awarded for this project, and all future years have been removed. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Where bilateral termination cannot be reached, the ICO must unilaterally terminate the project. Unilaterally terminated awards should follow the process identified **Termination Type 3: ICO-Terminations** to send the termination letter and revise the award.

- **Diversity Supplements:** Type 5 Diversity supplements may no longer be awarded. For ongoing awards, ICO's must remove the diversity supplement activities prior to issuing the next Type 5 for the parent award and include the following term in Section IV of the NOA of the parent grant. The ICO must revise the Diversity Supplement award to remove all outyears. If diversity supplement outyears were included in the previous NOA, the ICO must revise the prior year award to remove references to those outyear commitments.

  Term of Award: The diversity supplement associate with this project, [insert diversity supplement grant number], is being terminated. No additional funding will be awarded, and all future years have been removed. Research programs

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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 classes, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Funds issued for the Diversity Supplement may no longer be utilized and cannot be rebudgeted nor carried over to future years.

- **Conference Grants:** If a conference supported by an NIH grant focuses on scientific top ICO's that are unrelated to DEI, but the conference itself is targeted at a specific population (e.g., underrepresented groups), the ICO 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 ICO must terminate the award following the process in **Category 1**.
- **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 ICO's 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. ICO's 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 must be addressed under category 2 negotiations.
- **Administrative Supplement Requests:** Administrative supplement applications should be reviewed for any activities that are no longer NIH/HHS priorities/authority and modified as needed. ICO's do not need to retroactively review the competitive parent grant application– only the supplement application requires review.

Category 2B:

Prospective reviews by GM where the DEI and/or 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, ICO should consider using the Category 2 term of award but remove the negotiation language from the term. ICO's do not need to request revised materials from the recipients. However, the project title and/or abstract may need to be updated to remove any language that does not align with NIH/HHS priorities/authority. The changes must be noted in the grant file. Reminder: ICOs do not need to modify the historical record to modify language.

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- Resource Section
- Biosketch
- RPPRs
- Letters of Support

Category 2C: Subprojects/cores terminated by HHS.

ICO's do not need to terminate the subprojects/cores. The funds can be restricted and recovered, unless there is a negotiation where a new subproject/core is identified that does not violate the priorities of the agency. The following actions will occur in these cases:

- OPERA will restrict the funds associated with the project and notify the ICO.
- The ICO must revise the award to remove the subproject/core, only and must not issue a termination letter nor termination language within the terms and conditions. ICO
- The revised award must include the following term in Section IV.

> [Insert category from Appendix 3, verbatim]. Therefore, no additional funds may be used to support the activities under [insert subproject or core title], and all activities must cease, effective with the date of this revision. Funds used to support these activities will be disallowed and recovered. Funds issued for this subproject/core may no longer be utilized and cannot be rebudgeted nor carried over to future years.

Category 3: Project does not support any DEI or other activities that go against the HHS/NIH priorities.

- Action: ICO may proceed with issuing the award.

Category 4: Foreign Awards.

Note: Effective May 1, and until the details of the new foreign collaboration award structure are released, NIH will not issue awards to domestic or foreign entities (new, renewal or non-competing continuation), that include a subaward to a foreign entity. See NOT-OD-25-104.

4A. Agency priorities:

- South Africa: Note: Currently (April/May 2025), continue to hold award actions related to entities in South Africa until final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. ICOs may negotiate with recipients to remove activities in South Africa from ongoing awards as long as the project remains viable. **IMPORTANT NOTE: Funds may only be provided to entities in South Africa to support health and safety of human participants in clinical trials/clinical research.**
- China: Note: Currently (April/May 2025), hold on making awards to entities in China until the final determinations are made by NIH leadership. This applies to both monetary and non-monetary award actions. **IMPORTANT NOTE: ICOs may negotiate with recipients to remove activities in China from ongoing awards as**

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long as the project remains viable, or a suitable domestic replacement is identified. Funds may only be provided to entities in China to support health and safety of human participants in clinical trials.

4B. Countries of Concern:

- The State Department's countries of concern lists are updated regularly. Therefore, ICOs must check the list annually prior to making new, renewal, and noncompeting continuation awards. Additionally, out of an abundance of caution related to the United States national security threats, if a country is added to either of the two lists below, ICO's must submit a request through FACTs to obtain State Department clearance. If clearance is not received within 14 days, the award cannot be made until it is received (i.e., new, renewal, and noncompeting continuations).
- At this time, ICO's should note in FACTs when awards (new, renewal, non-competing continuation) involve entities on the following State Department lists:
  - Countries in which the government of has engaged in or tolerated "particularly severe violations of religious freedom": State Department Countries of Particular Concern
  - Countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism: State Sponsors of Terrorism
- Awards may only be issued once State Department clearance is obtained. Do not assume approval unless a response is received from the State Department. The staff guidance on FACTS clearance will be updated to reflect this change. This applies to all direct foreign awards and foreign collaborations (monetary and non-monetary).

OPERA has not included the Final Rule Restricting Transfer of Personal U.S. Data to Countries of Concern (please consider this list related to sensitive or PII data is involved for clinical trials/clinical research) or Office of Foreign Assets Control Sanctions List, as these are not factors in award decisions. In all cases, if there are questions contact the Fogarty International Center for expert assistance.

Termination Types:

As NIH implements the Director's agency's priorities, NIH will take various measures to integrate these priorities into the Institutes and Centers across the enterprise there are various types of terminations that may take place where the project cannot be renegotiated. As such, there steps that must be taken once the need for termination has been identified and/or provided.

Terminations that result from science that no longer effectuates NIH's priorities related to DEI, gender identity and other scientific areas do not require a formal appeals process. If a recipient requests an ICO to reconsider a termination action, the ICO can work with the recipient to determine whether the action will stand. All other terminations for noncompliance require the agency to include appeals language within the termination letter and NOA - appeal language.

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Type 1: 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 ICO 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 ICO must:

  - Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
    - Change the budget and project period end dates to match the date of the termination letter.
      - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - 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:

      This award is terminated effective [effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly phaseout 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 **60** days (non-human subjects) **120** days (human subjects and animals) after the end of this project.

NIH is taking this 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 ICO's do not need to report to OPERA on each action completed.
- When a terminated award must be reinstated, OPERA will notify the IC.
- ICOs must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction and will copy Alan Whatley on the request to the ICO.

Screenshot: Example of reinstatement. **Note – please make it clear that previous termination term has been deleted or is no longer applicable.**

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2: Type NIH OD

SECTION IV – AI SPECIFIC AWARD CONDITIONS – [redacted]

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: Effective with the date of this revised Notice of Award, funding for Project Number 1R21[redacted] is hereby fully reinstated; therefore, the termination letter dated 03/21/2025 is rescinded without conditions. Funds made available to UNIVERSITY [redacted] used to support "A[redacted] are no longer restricted and are available for use in accordance with the terms and conditions of the award.

Supersedes previous Notice of Award dated **03/22/2025**. All other terms and conditions still apply to this award.

****

Directed Terminations.

- The Immediate Office of the NIH Director evaluates a program and determines that a program must be terminated due to agency priorities (e.g., COMPASS, FIRST). OPERA receives a list from OD. In such cases, this determination could impact multiple projects and each individual project under the program must be addressed.
- 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 ICO must:

- Issue a revised NOA within 3 business days of the date the termination letter was issued to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - OPERA will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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

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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:

  This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

  Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

  This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

- When a terminated award must be reinstated, OPERA will notify the ICO.
- Once alerted, ICO's must issue a revised award and **replace** the previous termination language with the following term:
  - Effective with the date of this revised Notice of Award, funding for Project Number [insert grant number] is hereby fully reinstated; therefore, the termination letter dated [insert date] is rescinded without conditions. Funds made available to [insert institution name] used to support [insert the title of the project] are no longer restricted and are available for use in accordance with the terms and conditions of the award.
  - OPERA will coordinate with HHS PMS to lift the hard funds restriction.

Tracking Note: eRA provides OPERA with daily reports on NOAs issued, so ICO's do not need to report to OPERA on each action completed.

Type 3: ICO- Terminations.

- **ICO conducts a portfolio analysis and determines that a project no longer effectuates the agencies priorities.**

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- **Project cannot be renegotiated. The ICO must a letter to the recipient notifying them that the project will be terminated (see Appendix 8 for sample letter).**
  - 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.
      - The **ICO's** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
    - Remove all future years from the project, where applicable.
    - Include the following Termination Term in the revised NOA:

      This award is terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

      Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

      This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Type 4: Bilateral Terminations.

The recipient and the ICO agree that the project is no longer viable, and the project cannot be saved upon the removal of the research that no longer aligns with agency's priorities. As such the ICO must:

- Request a bilateral termination letter from the recipient agreeing to terminate the project on the basis that the project is no longer viable with the aims that need to be negotiated out of the project.

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- Issue a letter responding to the recipient's request notifying them that the ICO has accepted the bilateral termination and will issue a revised award to modify the project period end date to the date requested.
- ICO must issue a NOA to the recipient.
  - Change the budget and project period end dates to match the date of the termination letter.
    - The **ICO** will place a hard funds restriction on all PMS subaccounts as termination letters are issued. OPERAs Federal Financial Report Center (FFR-C) will deobligate the remaining funds after the Final FFRs are submitted. There is no deobligation action required from the ICO's.
  - 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:

    This award is bilaterally terminated effective [insert effective date]. [Insert category from Appendix 3, verbatim]. If appropriate, [RECIPIENT NAME] may request funds to support patient safety and animal welfare in support of an orderly phaseout of the project.

    Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination, or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

Separation of Duties Guidance:

OPERA has issued a Separation of Duties (SOD) waiver for all CGMOs, specific to the HHS Departmental Authorities termination actions, to allow IC CGMOs to work up and issue termination actions. Copy available in Teams.

Impacts on the Biomedical Workforce:

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- **NRSA Payback:** NIH recognizes that award terminations may prematurely end the training period for NRSA fellows and trainees. Fellows and trainees may not have received sufficient training to be qualified to perform the service requirement before the grant terminated or may be unable to find employment opportunities due to the termination. NIH will accept payback waiver requests from trainees and fellows impacted by terminations. See NIH GPS 11.4.3.4 for instructions on submitting waiver requests.

- **Early-Stage Investigators (ESI):**

    - Short Term Extension for ESI investigators: NIH will automatically extend the Early-Stage Investigator (ESI) eligibility period by four (4) months for all investigators whose ESI status was active during the period January 1, 2025, to May 31, 2025. NIH is implementing this short-term extension to assist ESI investigators – who are working under strict eligibility timelines – to remain competitive for NIH support. Updated ESI end dates will appear in eRA commons by June 1, 2025.

    - **Restoring ESI status:** Investigators lose their ESI eligibility when they successfully compete for and receive a substantial independent research award. In the event an investigator's first substantial independent research award is terminated within the first three years of the project period, the investigator can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. To be eligible, an investigator's grant may not have been terminated due to misconduct or ethical violations. See Requesting an Extension for instructions.

- **K award eligibility:** NIH has implemented a temporary exception to the NIH GPS Section 12.3.7, which generally limits eligibility for mentored career development (K) awards to those who have not previously been the recipient of such awards. NIH will allow individuals whose NIH-funded mentored career development awards were **ended on or after January 1, 2025**, to be eligible to apply for a new mentored career development award, contingent upon all other eligibility requirements being met. Investigators that meet all other NIH eligibility requirements for other mentored career awards may take advantage of applying for such awards to allow for the completion of the years that were remaining at the time the award ended.

Definition(s):

- **Gender-affirming care:** An array of services that may include medical, surgical, mental health, and non-medical services for transgender and nonbinary people. This includes, but is not limited to, therapy; mental health care; assistance with elements of a social transition (e.g., new name and pronouns, modification of clothing, voice training); evaluation of persistency of gender dysphoria, emotional and cognitive maturity, and coexisting psychological, medical, or social problems; puberty-suppressing medications; hormone therapy; and surgery. By way of clarification and not limitation, "gender-affirming care" includes patient care provided as part of research or education grants, including but not limited to routine services, ancillary services, outpatient services, inpatient services, and usual patient care received during the study.

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Health Disparities: Pending.

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Appendix 1 – HHS's Secretarial Directive on DEI-Related Funding – February 10, 2025.

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.**

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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, M.D., Acting Secretary

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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 ICO 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 ICO 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.

- 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs."
- Gender-Affirming Care: "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." **Reminder: At this time, do not terminate any grants related to gender identify/transgender without clearance from OER. All such actions must be approved before any terminations.**
- 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 (to be used for HHS/NIH OD directed terminations only): "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." **Note: ICO's may continue to support projects that funds general biology of coronavirus not linked to COVID-19. As ICO's conduct in-house analysis of project portfolios related to COVID the term may change. Please work with OPERA to develop standard terms based on the outcome of the analysis.**
- Climate Change: "Not consistent with HHS/NIH priorities particularly in the area of health effects of climate change."
- Influencing Public Opinion: "This project is terminated because it does not effectuate the NIH/HHS' priorities; specifically, research related to attempts to influence the public's opinion."

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

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

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Appendix 5 – Workflow for NOFO Forecasts and NOFO Approvals

- **Prioritization of NOFOs**

Owner	Action
ICO	• Sends a priority list of upcoming NOFOs in two categories: **1)** those that already have Concept Clearance (Option A)[1]. **2)** those requiring Concept Clearance (Option B). Note: This is a temporary step while process is being refined.
Guide	• Maintains the data on ICO records, approvals needed (for example concept clearance), and priorities for publication in ICO Guide priorities spreadsheet.

- **Creation of Forecast Records**

Owner	Action
ICO	• Creates a **forecast** in FOAM for NOFOs prior to concept clearance and at least **6 months** prior to the desired NOFO publication date. Forecast is used for approval of the concept by NIH and HHS. Note: Forecast information will become publicly available in Grants.gov after concept clearance is obtained. ○ Create a **Forecast** record. ○ Fill in required fields (red asterisks): NOFO type (PAR, PA, etc.), Title, Contact. ○ Click "Save". ○ Click "Create NOITP" button within the NOFO record. ○ Select most recent *Forecast Template*. ○ Click "Save". ○ Go to *Content* and fill in required fields (red asterisks). ○ Title, estimated date, related information (publication, first application, first awards, project start), eligibility – note, activity code not required. ○ Note: the forecast *Description* section is what NIH Leadership will be reviewing and requires the appropriate ICO leadership approval. ○ Save record and notify the Guide when the forecast is ready for leadership approval (see below). • Sends email to the Guide mailbox when ready for leadership approval ○ NIH Guide (NIH/OD) nihguide@OD.NIH.GOV ○ Subject: NOITP ###-##-##-###– [IC Name] – [Desired Clearance Date] ▪ Note: the number is important because of the variety of draft versions in FOAM. ▪ Plan to implement FOAM task in future to remove dependence on email.

[1] For programmatic concepts that have already undergone concept clearance within the last five years, but the NOFO has not been published (for example, NOFO pending in FOAM or not yet drafted).

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- **Preparing Forecasts for Leadership Approvals**

Owner	Action
Guide	• Indicates that the forecast is ready for review on the tracking spreadsheet (if not done through FOAM task).
Leadership Approval Contact	• Places relevant fields on a leadership approval spreadsheet and the Acting DDER is alerted when entries are ready for review.

- **(Acting) DDER and NIH Director Approvals**

Owner	Action
(Acting) DDER	• Reviews entries on leadership review spreadsheet and updates with approval outcome. • Notifies ICOs regarding the forecasts that are **not approved.**
Leadership Approval Contact	• Monitors the review spreadsheet and adds entries and dates on tracking spreadsheet • Notifies ICOs of **approvals** and indicates next steps.
ICO	• Archives the FOAM entries for those not approved. • Uploads the approval document into FOAM.

- **HHS Approval & Concept Clearance (if needed)**

Option A: After NIH Approval for NOFOs not requiring Concept Clearance

Owner	Action
Guide	• Sets NOITP status to "published" in FOAM once the content has been fully approved. • Notifies **OPERA** of the status via email.
OPERA	• Sends Forecast report to HHS[2] . • Records forecasting information in Grants.gov (forecast is publicly available at Grants.gov, but not NIH Guide).
ICO	• Works on NOFO development: ○ Convert to the newest template in FOAM. ○ Ensure that the NOFO record indicates in Key Attributes that Concept Clearance has been obtained. ○ Check that the approval document(s) has been uploaded in FOAM. ○ For NOFOs in various stages of development, follow the standard processes for content development and approvals. ○ For NOFOs with previous OER approvals, ICO should upload a "compare documents" of the NOFO drafts into FOAM to verify that the ICO did not change any text except to align with current agency priorities. **Note:** FOAM has a compare documents feature.

[2] Until the Grants.gov Forecast functionality has been deployed in FOAM, OPERA will assist with manual updates of all of NIH's NOFOs to Grants.gov monthly (by the 5th of each month—if the 5th falls on a holiday or weekend, we will act by the next business day).

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	○ Responds to all approval comments and tasks and indicates that the final NOFO draft is ready for NIH leadership approval.

Option B: After NIH Approval for NOFOs requiring Concept Clearance

Owner	Action
ICO	• After receiving NIH leadership approval, proceed with obtaining Concept Clearance. • Enters the Concept Clearance information in the Key Attributes of the FOAM record.
	• If **no changes** to the forecast are required after Concept Clearance, the steps described in Option A should be followed. • If the content of the forecast changes after Concept Clearance, the content must go back through leadership approvals.

- **NIH Leadership Review of Completed NOFOs**

Owner	Action
Leadership Approval Contact	• Downloads completed NOFOs to a folder (with hyperlinks embedded in the spreadsheet). • Places relevant fields on a NOFO NIH Leadership Approval spreadsheet. • Alerts NIH Leadership when entries are ready for review.
(Acting) DDER	• Notifies ICOs regarding the NOFOs that are not approved.
Leadership Approval Contact	• Notifies ICO, Guide, OPERA of approvals.
Guide	• Enters positive approvals in the FOAM record and publishes the NOFO.

Questions:

Inquiries about the Forecast requirements and processes should be directed to: Division of Grant Systems Integration, Office of Policy for Extramural Research Administration Office of Extramural Research: operasystemspolicy@nih.gov.

Inquiries about FOAM should be directed to the Guide: NIH Guide (NIH/OD) nihguide@OD.NIH.GOV.

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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 ICO's review the content of Other Support submissions?**

   Other Support is used to disclose the PIs ongoing activities and support and should not be modified. ICO's 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 ICO notify the recipient that the Type 4 will not be issued?**

   In these cases, ICO's must contact OPERA, and OPERA will issue a termination letter. Type 4 awards are subject to the availability of funds and/or agency priorities.

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

   The ICO should not contact recipients to request any additional information to address SEAR flags, because the project is being terminated. ICO's 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 ICO 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?**

   Yes, NIH will allow recipients of terminated K awards to submit applications for new K awards.

6. **If a PD/PI receives a 'substantial NIH independent research award' and loses ESI status, but the award is terminated, can the PD/PI have their ESI status reinstated?**

   Yes. Investigators can request the reinstatement of ESI status, using the ESI Extensions request tool in eRA commons. See Requesting an Extension for instructions.

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

   Yes, ICO's must use the exact language provided in Appendix 3, with no edits.

8. **Can ICO's make awards for applications that came in under a NOFO that has expired (not unpublished) if the NOFO's sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities?**

   No. Whether unpublished or expired, if the sole purpose was DEI or another category that does not effectuate the NIH/HHS priorities, ICO's cannot make the award. For updated information on

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NOFOs, CGMOs must contact their DEA rep.

9. **If a NOFO is taken down for modification, and re-posted, can ICO's issue awards in response to that NOFO?**

   Yes. If the NOFO has been modified and reposted, ICO's may proceed with making awards after confirming that the award aligns with agency priorities.

10. **If an ICO is modifying a Type 5 restore full amount, does the ICO need to conduct a review of the project activities as outlined in this guidance?**

    Yes. All monetary revisions are subject to this guidance.

11. **Can ICO's approve requests from recipients to modify the project title?**

    Requests to change project titles must be submitted as a prior approval request. Changes to titles may only be made in the context of negotiations to remove activities/language that do not align with HHS/NIH priorities/authority. Title changes should only be made alongside associated changes to the abstract and specific aims.

12. **When ICO's receive questions from recipients regarding HHS terminations, what should they do?**

    ICO's should not engage in discussions with recipients regarding HHS directed terminations. ICO's must direct recipients to submit any appeals to Dr. Memoli, as outlined in the termination letter.

13. **For terminations where the ICO is making the determination, who is listed as the point of contact for appeals?**

    An ICO determination that an award no longer aligns with agency priorities is not appealable. Therefore, appeals language is not included in the termination term. Recipients may contact the IC Director to request a reconsideration of the ICO determination.

14. **What is the difference between an HHS-directed termination vs. and ICO or OD determination to terminate a project?**

    For HHS directed terminations, the template letter and appeals language were provided by HHS, and must be used as is. When an ICO or the OD determines that an award no longer aligns with agency priorities, the termination is made in accordance with 2 CFR 200.340(a)(4). This is not a termination for material failure to comply with the terms and conditions of award and is not appealable.

15. **When will the Final RPPR become available for recipients to prepare and submit?**

    The F-RPPR link will open once the project period has ended.

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16. **Can recipients draw down funds after the stated termination date?**

    For activities that were incurred on or before the termination date, with supporting documentation, NIH will approve the payment. For costs after the project period end date, outside of patient safety and animal welfare, costs will not be approved.

17. **When will the Federal Financial Report (FFR) become available in PMS for recipients to submit?**

    The FFR will become available once the project period has been updated via a Notice of Award. Recipients should direct any questions to PMS or the OPERA FFRC.

18. **Will recipients have the standard 120-day period following the termination date to submit closeout reports?**

    Because there are no new activities after the date of termination, NIH is directing that all closeout reports be submitted within 60 days of the termination unless animals or human subjects are involved.

19. **If an ICO negotiates a change in a foreign site (e.g., South Africa to Nigeria), can the funds be rebudgeted from the original site to a new site?**

    Yes. Funds can be rebudgeted to conduct the activities at a new site as long as the site is domestic. All new foreign collaborations will need to follow the new structure once rolled out. If research aims are fully removed from a project, the funds cannot be rebudgeted for another purpose.

20. **For awards that were terminated before the term and condition of award was modified to provide instructions for requesting approval of drawdowns, how should ICO's notify the recipient of the process?**

    When ICO's receive questions from recipients about the process for requesting drawdowns, the ICO must notify the recipient that they should contact the OPERA FFRC (OPERAFFRInquiries@od.nih.gov) for prior approval. The request must include details related to human subjects or animal welfare or outline that the costs were incurred prior to the termination date. The recipient must provide supporting documentation.

21. **If a recipient requests prior approval to change a performance site from South Africa to another location, can the ICO approve the change?**

    Yes. ICO's may approve change to move activities from South Africa to another site. At this time, awards involving South Africa remain on hold. ICO's should not initiate negotiations or restrict funds.

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22. Does the COVID category apply to long-COVID and pandemic preparedness research? Or is it focused only on the immediate COVID-19 pandemic response.

The COVID category relates to awards made to address the immediate COVID-19 pandemic response. Awards to support general biology of coronavirus, long COVID and pandemic preparedness, at this time, may continue.

23. If a letter of support on a training grant references a university resource for DEI, but the abstract and aims do not include any DEI activities, does the letter of support need to be revised?

No. Under the concepts outlined in Category 2B, updated documents are not required to modify language when there are no DEI activities under the project.

24. For diversity fellowships awarded prior to January 20, 2025, are recipients permitted to activate their awards?

Yes. Recipients may activate the fellowship. ICO's must review these awards in accordance with this staff guidance, and future funds must not be awarded.

25. For joint NIH-NSF programs, where the initial application came in to NIH via a 'dummy' NOFO, can ICO's negotiate the award to remove any activities that do not align with NIH/HHS priority/authority?

Yes. These awards must be reviewed, and any unallowable activities must be negotiated out.

26. If NIH funds were awarded to support conference attendance, and the conference has a session on DEI, can the recipient use the NIH funds to attend?

No. NIH funds may not be used to pay for participation in a conference that includes DEI sessions or activities.

27. If a conference proposes a session on DEI (e.g., DEI Power Hour), can the ICO negotiate with the recipient to remove those activities from the conference agenda?

Yes. The ICO can negotiate with the applicant/recipient to remove the DEI activities.

28. For programs that have been terminated, in whole (e.g. MOSAIC K99/R00), will there be any central announcement, or should ICO's proceed with revising awards in accordance with the staff guidance.

In these cases, the NOFO will be unpublished. There will not be any other announcement. ICO's should take action on the awards as outlined in this staff guidance.

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Appendix 7 – Managing PMS Hard Funds Restrictions

OPERA directs PMS to hard funds restrict awards terminated as a result of agency priorities and HHS authorities.

Recipients are required to request approval from OPERA (OPERAFFRInquiries@od.nih.gov) before any draw that occurs after the termination. The request must include details related to human subjects or animal welfare and provide supporting documentation. These are the only approvals that will be issued. OPERA will work with the ICO to facilitate approvals and facilitate lifting restrictions in PMS. After approval is issued, the recipient can request the drawdown in PMS. Note: Any other costs that are not related to human subject protection or animal welfare will not be approved. No exceptions.

Recipients are also required to request approval from OPERA to lift the restriction for payments of costs incurred on or before the date of the termination. For costs incurred, with supporting documentation, on or before the date of the termination, OPERA will work with PMS to lift the restriction as appropriate.

Note: Balances reported to HHS will change, as drawdowns are approved as outlined above. Reports to HHS will be updated as balances are modified. OPERA is responsible for maintaining up to date information for HHS reporting.

When recipients draw funds in PMS, they normally request funds from multiple awards within a single draw request. For awards terminated as a result of agency priorities and HHS authorities, recipients cannot request funds from multiple awards within a single draw request. Each draw request must contain only one terminated award. If a recipient combines a draw request for a terminated award with any other award, the request will be rejected.

Entity Restrictions:

At times, HHS or NIH may place a hard funds restriction on an entity in PMS, at the entity level, during compliance reviews. When this occurs, OPERA will notify ICO's. During the restriction period, ICO's should hold awards to the institution until the restriction is lifted.

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Appendix 8 – Template ICO Termination letter.

[Address block & date]

[Authorized Organization Representative]:

Funding for Project Number [INSERT] 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 [INSERT DATE], 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. [insert termination category language (e.g., DEI) verbatim]. 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.

This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to [IC Director Name], Director, [IC Name].

Sincerely,

IC CGMO

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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.

Nos. 25-1611, 25-1612

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN PUBLIC HEALTH ASSOCIATION; IBIS REPRODUCTIVE HEALTH; INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS (UAW); BRITTANY CHARLTON; KATIE EDWARDS; PETER LURIE; NICOLE MAPHIS,

Plaintiffs-Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the United States Department of Health & Human Services,

Defendants-Appellants.

COMMONWEALTH OF MASSACHUSETTS; STATE OF CALIFORNIA; STATE OF MARYLAND; STATE OF WASHINGTON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF DELAWARE; STATE OF HAWAII; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF WISCONSIN,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JAY BHATTACHARYA, in the official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH; NATIONAL CANCER INSTITUTE; NATIONAL EYE INSTITUTE; NATIONAL HEART LUNG AND BLOOD INSTITUTE; NATIONAL HUMAN GENOME RESEARCH INSTITUTE; NATIONAL INSTITUTE ON AGING; NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM; NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES; NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING; EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION

DISORDERS; NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH; NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES; NATIONAL INSTITUTE ON DRUG ABUSE; NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES; NATIONAL INSTITUTE OF MENTAL HEALTH; NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES; NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE; NATIONAL INSTITUTE OF NURSING RESEARCH; NATIONAL LIBRARY OF MEDICINE; NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES; JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES; NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH; NIH CENTER FOR SCIENTIFIC REVIEW,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

APPENDIX - VOLUME V

BRETT A. SHUMATE
Assistant Attorney General

LEAH B. FOLEY
United States Attorney

DANIEL TENNY
BENJAMIN C. WEI
Attorneys, Appellate Staff
Civil Division, Room 7235
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TABLE OF CONTENTS

ADDENDUM

Memorandum and Order on
Subject Matter Jurisdiction (25-cv-10814 Dkt. No. 105) A1

Memorandum and Order on
Motion to Dismiss (25-cv-10787 Dkt No. 84) A29

Transcript of Consolidated June 16, 2025, Bench Trial
(25-cv-10787 Dkt. No. 143) (25-cv-10814 Dkt. No. 156) A73

Partial Final Judgment 25-cv-10814
(25-cv-10814 Dkt. No.151) A161

Partial Final Judgment 25-cv-10787
(25-cv-10787 Dkt. No. 138) A163

Findings of Fact, Rulings of Law, and
Order for Partial Separate and Final Judgment
(25-cv-10787 Dkt. No. 151) (25-cv-10814 Dkt. No. 163) A166

Order Denying Motion to Stay Pending Appeal
(25-cv-10787 Dkt. No. 147) (25-cv-10814 Dkt. No. 160) A269

VOLUME I

Docket Report for *American Public Health Association, et al. v. National Institutes of Health, et al.*, Case No. 25-cv-10787 (APHA Case) A275

Docket Report for *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, Case No. 25-cv-10814 (States Case) A328

Complaint in APHA Case
(APHA Case Dkt. No. 1) A380

Amended Complaint in States Case
(States Case Dkt. No. 75) A458

Notice of Appeal APHA Case
(APHA Case Dkt. No. 139) A550

Notice of Appeal States Case
(States Case Dkt. No. 152) A553

NIH Review of Agency Priorities Based on the New Administration's Goals
February 12, 2025 (NIH_GRANTS_9) A556

Supplemental Guidance to Memo
February 13, 2025 (NIH_GRANTS_16) A557

Directive on NIH Priorities
February 21, 2025 (NIH_GRANTS_2930-31) A558

Award Assessments for Alignment with Agency Priorities
March 4, 2025 (NIH_GRANTS_2135-72) A560

Award Revision Guidance
March 13, 2025 (NIH_GRANTS_1957-58) A598

Award Assessments for Alignment with Agency Priorities
March 25, 2025 (NIH_GRANTS_3216-30) A600

Alignment with Priorities
May 7, 2025 (NIH_GRANTS_3547-81) A615

Alignment with Priorities
May 15, 2025 (NIH_GRANTS_3516-46) A650

Transcript of Consolidated May 8, 2025, Hearing
(25-cv-10814 Dkt. No. 107) A681

Transcript of Consolidated May 13, 2025, Hearing
(25-cv-10814 Dkt. No. 110) A709

Transcript of Consolidated June 3, 2025, Status Conference
(25-cv-10814 Dkt. No. 107) A740

VOLUME II - DECLARATIONS

Declaration Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-19	Declaration of Plaintiff Brittany Charlton	All.	A768
38-20	Declaration of Plaintiff Katie Edwards	1–13	A864
38-21	Declaration of Plaintiff Nicole Maphis	1–7	A876
38-22	Declaration of Plaintiff Peter Lurie	1–6	A883
38-23	Declaration of Georges C. Benjamin On behalf of Plaintiff American Public Health Association (APHA)	All.	A888
38-24	Declaration of Plaintiff Ibis Reproductive Health	1–10	A976
38-25	Declaration of Neal Sweeney On behalf of Plaintiff United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)	All.	A985
38-26	Declaration of Jeremy Berg	All.	A991
38-27	Declaration of Scott Delaney	All.	A1009
38-28	Declaration of APHA Member 1	1–10	A1091
38-29	Declaration of APHA Member 2	1–10	A1100
38-30	Declaration of APHA Member 4	1–9	A1109
38-31	Declaration of APHA Member 5	1–9	A1117
38-32	Declaration of APHA Member 7	1–24	A1125
38-33	Declaration of APHA Member 9	All.	A1148
38-34	Declaration of APHA Member 10	1–9	A1204

38-35	Declaration of UAW Pre-Member 1	1–7	A1212
38-36	Declaration of UAW Pre-Member 7	1–7	A1218
38-37	Declaration of UAW Member 3	1–8	A1224
38-38	Declaration of UAW Member 9	1–5	A1231
38-39	Declaration of UAW Member 10	1–8	A1235
38-40	Declaration of UAW Member 11	All.	A1242
38-41	Declaration of UAW Member 12	1–7	A1286
38-42	Declaration of UAW Member 13	1–5	A1292
72-3	Supplemental Declaration of Scott Delaney	All.	A1296
72-4	Supplemental Declaration of Jeremy Berg	All.	A1305
72-10	Supplemental Declaration of Plaintiff Nicole Maphis	1–3	A1316
72-12	Supplemental Declaration of Plaintiff Katie Edwards	All.	A1318
103-3	Second Supplemental Declaration Of Scott Delaney	All.	A1322
103-4	Second Supplemental Declaration Of Katie Edwards	All.	A1352

VOLUME III - EXHIBITS

Exhibits Index			
25-cv-10787 ECF No.	Description	ECF Page Range	Page
38-01	NIH Webpage titled "Institutes at NIH"	All.	A1356

38-02	NIH webpage titled "Budget" (last updated on October 3, 2024)	All.	A1357
38-03	NIH webpage for Notice Number: NOT-OD-25-084, "NIH Operates Under a Continuing Resolution" (published April 3, 2025)	All.	A1360
38-04	Excerpt of NIH-wide Strategic Plan, Fiscal Years 2021-2025	All.	A1361
38-05	Excerpt of April 2024 NIH Grant Policy Statement	All.	A1405
38-06	March 14, 2025, Article from *The Atlantic* by Katherine J. Wu, titled "The NIH's Grant Terminations are 'Utter and Complete Chaos.'"	All.	A1424
38-08	Transcript of April 3, 2025, Deposition of Michelle Bulls in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 48-50, 68-76, 92-93, 99-102	A1439
38-09	Transcript of April 3, 2025, Deposition of Liza Bundesen in *Washington v. Trump*, No. 2:25-cv-00244-LK (W.D. Wash. 2025)	ECF Pages 3, 38-39	A1458
38-16	NIH Minority Health and Health Disparities Strategic Plan 2021-2025	All.	A1461
72-01	NIH webpage titled "Contracts"	All.	A1499
72-05	March 2025 Kirschstein NRSA Funding Opportunity	All.	A1506
72-06	January 2025 Kirschstein NRSA Funding Opportunity	All.	A1526
72-07	NIH webpage titled "Updates to NIH Institutional Training Grant Applications" (last updated March 25, 2025)	All.	A1542

72-08	March 11, 2025, Memo from Matthew Memoli with subject line "Initial Actions Regarding President Trump's Executive Orders – INFORMATION"	All.	A1550
72-09	April 8, 2021, Document Titled "Research General Terms and Conditions Agency Specific Requirements for the National Institutes of Health (NIH)"	All.	A1597
138-1	May 27, 2025, Spreadsheet of Grants	All.	A1603
138-2	June 13, 2025, Spreadsheet of Grants	All.	A1619

VOLUME IV - EXCERPTS FROM THE ADMINISTRATIVE RECORD

Excerpts from the Administrative Record
(from NIH_GRANTS_00001 to NIH_GRANTS_03578) A1636

VOLUME V - ADDITIONAL EXCERPTS FROM THE ADMINISTRATIVE RECORD

Additional Excerpts from the Administrative Record
(from NIH_GRANTS_03585 to NIH_GRANTS_05676) A2334

March 11, 2025

Center for Innovative Public Health Research
Camille Labranche
Authorized Organizational Official
160 Avenida Victoria
San Clemente, CA 92672
Email: camille@innovativepublichealth.org

Dear Camille Labranche

Funding for Project Number 5R01NR020846-02 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 June 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 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]

[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.

no corrective action is possible here. The premise of Project Number 5R01NR020846-02 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 *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 Brian Albertini, CGMO – NINR

Director, Office of Policy for Extramural Research Administration, OER

[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).

National Institutes of Health
Office of Extramural Research

March 18, 2025

Julie C. Tang
The Regents of the University of California, San Francisco
julie.tang@ucsf.edu

Dear Julie C. Tang:

Effective with the date of this letter, funding for Project Number 1R01 AI186641-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 14, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

03/19/2025

Brian Line
JOHNS HOPKINS UNIVERSITY
eawards@jhu.edu

Dear Brian Line:

Effective with the date of this letter, funding for Project Number 5R01AI172092-03 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 Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

03/19/2025

Hang McLaughlin
UNIVERSITY OF MINNESOTA
awards@umn.edu

Dear Hang McLaughlin:

Effective with the date of this letter, funding for Project Number 5R01CA253244-03 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 06/01/2022, 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 Crystal Wolfrey, Chief Grants Management Officer, National Cancer 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)

National Institutes of Health
Office of Extramural Research

03/19/2025

Benjamin Wichterman
UNIVERSITY OF MINNESOTA
awards@umn.edu

Dear Benjamin Wichterman:

Effective with the date of this letter, funding for Project Number 5R01CA265945-03 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.

[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 Crystal Wolfrey, Chief Grants Management Officer, National Cancer 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)

03/20/2025

Magdalene Cho
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
cgrasteam@ucsf.edu

Dear Magdalene Cho:

Effective with the date of this letter, funding for Project Number 5R01DA052016-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/01/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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 Pamela Fleming, Chief Grants Management Officer, National Institute on Drug Abuse
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)

National Institutes of Health
Office of Extramural Research

03/20/2025

Gregory Sorensen
UNIVERSITY OF MARYLAND BALTIMORE
nga@umaryland.edu

Dear Gregory Sorensen:

Effective with the date of this letter, funding for Project Number 5R01DE032225-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 09/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, 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)

National Institutes of Health
Office of Extramural Research

03/20/2025

Shawnya Robinson
CHILDREN'S RESEARCH INSTITUTE
grantsandcontracts@childrensnational.org

Dear Shawnya Robinson:

Effective with the date of this letter, funding for Project Number 5R01HD114134-02 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 07/01/2024, 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, on behalf of Margaret Young, Chief Grants Management Officer,
National Institute of Child Health & Human Development
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)

National Institutes of Health
Office of Extramural Research

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.

[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]

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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)

03/20/2025

R. David Paul
UNIV OF NORTH CAROLINA CHAPEL HILL
resadminosr@unc.edu

Dear R. David Paul:

Effective with the date of this letter, funding for Project Number 5R01HL149778-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 03/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

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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

[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)

03/20/2025

Darlene Holte
UNIVERSITY OF WISCONSIN-MADISON
NIH@rsp.wisc.edu

Dear Darlene Holte:

Effective with the date of this letter, funding for Project Number 5R01MD018571-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 03/01/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

03/20/2025

HOLLY ELIZABETH OSBORNE
STANFORD UNIVERSITY
NIHAWARDS@lists.stanford.edu

Dear HOLLY ELIZABETH OSBORNE:

Effective with the date of this letter, funding for Project Number 5R01MH115349-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/16/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

03/20/2025

TRACEY LARKIN
UNIVERSITY OF MICHIGAN AT ANN ARBOR
swhite-gov@umich.edu

Dear TRACEY LARKIN:

Effective with the date of this letter, funding for Project Number 5R01MH115765-05 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 05/01/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 14, 2025

Jennifer Scerri
Stanford University
Email: jscerri@stanford.edu

Dear Jennifer Scerri:

Effective with the date of this letter, funding for Project Number OT2 OD025276-03 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 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) 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 *All of Us* Research Program will set up an official meeting 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,

LaMeshia Billington
Other Transaction Agreements Officer
All of Us Research Program

cc: Michelle G. Bulls, Director
Office of Policy for Extramural Research Administration, OER

[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)

National Institutes of Health
Office of Extramural Research

March 18, 2025

Olive T. Giovannetti
The Regents of the University of California, San Francisco
Olive.giovannetti@ucsf.edu

Dear Olive T. Giovannetti:

Effective with the date of this letter, funding for Project Number 1R01 AI181732-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 18, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 20, 2025

Stephanie Boman
The Ohio State University
Boman18@osu.edu

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, 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)

March 20, 2025

Trudy M. Riley
Virginia Polytechnic Institute & State University
ospdirector@vt.edu

Dear Trudy M. Riley:

Effective with the date of this letter, funding for Project Number 1R21 AA031548-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 17, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, National Institute on Alcohol Abuse and Alcoholism
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 21, 2025

Aimee Barnard
University of Southern California
barnard@usc.edu

Dear Aimee Barnard:

Effective with the date of this letter, funding for Project Number 1R21 MD019829-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 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.

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

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

National Institutes of Health
Office of Extramural Research

March 21, 2025

Alexis Wright
University of California, Santa Barbara
wright@research.ucsb.edu

Dear Alexis Wright:

Effective with the date of this letter, funding for Project Number 1R21 MH135234-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on September 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

[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

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)

National Institutes of Health
Office of Extramural Research

March 21, 2025

Garrett M. Steed
The Regents of the University of Colorado
xenia@ucdenver.edu

Dear Garrett M. Steed:

Effective with the date of this letter, funding for Project Number 1R21 MH135779-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 15, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based 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.

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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.

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]

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The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[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)

From: Memoli, Matthew (NIH/OD) [E]
To: Lorsch, Jon (NIH/NIGMS) [E]; Bulls, Michelle G. (NIH/OD) [E]
Cc: Smith, Brad M. EOP/DOGE; McElroy, James (NIH/OD) [E]
Subject: Terminations
Date: Wednesday, March 12, 2025 2:00:56 PM
Attachments: Terminated Grants 3-12.xlsx

Good afternoon,

Attached is a list of grants that should be terminated for not being aligned with current HHS/NIH priorities. If possible, please terminate by COB today.

Thank you,

Matt

--

Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sponsoredprojects@uoregon.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 2:00:00 PM

Re: F31GM151758-02

Dear Ms. Austin, Melodie,

As Business Official for the above referenced award (PI AMANDA DAVIS), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: odixit@health.ucsd.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM068524-22

Dear Oolka Dixit,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: osp@stonybrook.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM102778-13

Dear Radgowski, Celeste,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: awards@umn.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM119955-08

Dear Mr. Skurich, Elliot,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Barbara.Gardner@tufts.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM133314-06

Dear Gardner, Barbara,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: uw-aor@u.washington.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: K99GM141364-02

Dear Rhodes, Carol,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Jeffrey.Schieder@buffalo.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM154101-02

Dear Schieder, Jeffrey,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research With Activities Related to Diversity (ReWARD) (R01)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: anita.yip2@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM138700-05

Dear Anita Yip,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: renuka.sippy@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM144250-04

Dear Ms. Sippy, Renuka,

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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: maria.reyes@csulb.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM138075-04

Dear Maria Reyes,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Doctorate** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: CA737@rutgers.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM140951-04

Dear Timothy Kirby,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ospa@umbc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM144876-03

Dear Deborah Waters,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ras@nmsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM148394-02

Dear Ms. Alisha A. Giron,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Bigbie, Stacy
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM152941-02

Dear Stacy Catanach,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Leading Equity and Diveristy in the Medical Scientist Training Program (LEAD MSTP)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ORS-AORContact@lists.hawaii.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM141986-04

Dear Sharleen Andreshak,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sdsurfawards@sdsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM149430-02

Dear Jennie Amison,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sgartner@calpoly.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM154620-01

Dear Susanne Gartner,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sponsoredprograms@unc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: UE5GM157254-01

Dear Jones, Nathan,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Advancing Research Careers (ARC)** 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.

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If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Palmer, Richard (NIH/NLM) [E]
To: Bill Hersh; Lisa Karstens
Cc: Wang, Yanli (NIH/NLM) [E]
Subject: RE: R25 Summer Program Details
Date: Thursday, May 8, 2025 5:27:00 PM

Dear Lisa and Bill,

I hope your summer program is going well. Unfortunately, I must share some news with you about the *Short-Term Research Education Experiences to Attract Talented Students to Biomedical Informatics/Data Science Careers and Enhance Diversity* initiative.

Due to current agency priorities, this program will be terminated at the end of the current grant cycle. At this time, no additional noncompeting continuation (Year 4) awards will be made. While agency directions are always subject to change, this is the current status, and I wanted to provide you with advance notice so that you can plan accordingly in the remaining months of the current award year.

NLM sincerely thanks you for your dedication and the hard work that has made this initiative a success. Your efforts have played a vital role in advancing NLM's goal of advancing a biomedical informatics and data science training.

Thank you again for your partnership and for your ongoing commitment to this field.

Sincerely,
Richard

Richard C. Palmer, Dr.P.H., J.D.
Director, Division of Extramural Programs (Acting)
National Library of Medicine
National Institutes of Health
Rockledge I, Room 500

Phone: 301-496-4254
Email: richard.palmer@nih.gov

From: Bill Hersh <hersh@ohsu.edu>
Sent: Wednesday, March 19, 2025 2:04 PM
To: Palmer, Richard (NIH/NLM) [E] <richard.palmer@nih.gov>
Cc: Wang, Yanli (NIH/NLM) [E] <yanli.wang@nih.gov>; Lisa Karstens <karstens@ohsu.edu>; Andrea Ilg <ilgan@ohsu.edu>; Vishnu Mohan <mohanv@ohsu.edu>
Subject: [EXTERNAL] Re: R25 Summer Program Details

Richard,

Thanks for the update, and glad to hear that NLM is supportive of the program.

I don't know if word made it to you, but we did make a PI switch for this grant, with Lisa Karstens now the contact PI and me the MPI. (We did the same with the T15 and Vishnu Mohan, with me MPI of that one as well.)

To answer your questions:

1. We are in the process of interviewing and selecting trainees right now. Some offers have already been made, and the rest will be made next week.
2. Our program will run from June 16 to September 5 this year.
3. Most of our trainees are from the Portland area, although many go to school outside Oregon and come home for the summer. We may take some from outside Oregon if they are a good fit for the project they match to.

Happy to provide any additional information.

Bill

From: Palmer, Richard (NIH/NLM) [E] <richard.palmer@nih.gov>
Date: Wednesday, March 19, 2025 at 7:44 AM
To: Bill Hersh <hersh@ohsu.edu>
Cc: Wang, Yanli (NIH/NLM) [E] <yanli.wang@nih.gov>
Subject: [EXTERNAL] R25 Summer Program Details

Dear Bill:

I would like to inform you that Dr. Merly Sufian has officially retired, and Dr. Yanli Wang (yanli.wang@nih.gov) will now serve as the interim program contact for your R25 grant until June. Please direct any programmatic questions to Dr. Wang or reach out to your assigned Grants Management Specialist listed in eRA for administrative/budget inquiries.

As you are probably aware, NIH is evaluating all programs to ensure alignment with government priorities. At this time, no decision has been made about the R25 program, and you should continue with all activities. Unfortunately, this assessment is occurring as you are planning for your next cohort, which is untimely. NLM is working to ensure that R25 summer programs remain unaffected.

To help me better understand your program, please provide the following information:

1. The date in which you plan to select summer trainees.
2. The start and end dates of this year's program.
3. Whether you intend to select trainees from outside your geographic area/cover travel expenses.

Please respond to me directly at your earliest convenience.

Sincerely,
Richard

Richard C. Palmer, Dr.P.H., J.D.
Acting Director, Division of Extramural Programs
National Library of Medicine
NIH/DHHS

Email: richard.palmer@nih.gov
Phone: 301-496-4254

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From: Smith, Brad M. EOP/DOGE
To: Memoli, Matthew (NIH/OD) [E]
Subject: [EXTERNAL] RE: NOFOs
Date: Saturday, February 22, 2025 4:34:04 PM

Matt,

Thanks for the update. We are all very grateful for your leadership.

Best,
Brad

From: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Sent: Saturday, February 22, 2025 12:05 PM
To: Smith, Brad M. EOP/DOGE <Brad.M.Smith@doge.eop.gov>
Subject: Re: NOFOs

Hi Brad,

After my review these all need to come down. Some of the projects may be able to be modified to properly address our current priorities, but in their current form they are not in line with what NIH would like to be doing right now. I have instructed OER to take them all down.

Thanks,
Matt

Get Outlook for Mac

From: Smith, Brad M. EOP/DOGE <Brad.M.Smith@doge.eop.gov>
Date: Saturday, February 22, 2025 at 11:36 AM
To: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Subject: [EXTERNAL] NOFOs

Matt,

Thanks so much for your time yesterday. Per our conversation, below are a number of NOFOs that it may be worth your team reviewing to make sure they align with your directive and priorities. We 100% defer to your team on whether each of these align with your directive, but I thought you might find this list helpful as you consider where to focus your review:

https://grants.nih.gov/grants/guide/pa-files/PAR-23-112.html
https://grants.nih.gov/grants/guide/pa-files/PAR-22-145.html

https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html
https://grants.nih.gov/grants/guide/pa-files/PAR-23-292.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-077.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-109.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-157.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-158.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-098.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-201.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-237.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-240.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-241.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-317.html
https://grants.nih.gov/grants/guide/pa-files/PAR-26-001.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-003.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-NR-25-004.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-005.html

Best,
Brad

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From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Osp@binghamton.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 2:00:00 PM

Re: F31GM148053-03

Dear Dearin, Jason,

As Business Official for the above referenced award (PI SAMANTHA BENJAMIN), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sponsoredprojects@uoregon.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 2:00:00 PM

Re: F31GM151758-02

Dear Ms. Austin, Melodie,

As Business Official for the above referenced award (PI AMANDA DAVIS), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sponsoredprojects@uoregon.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 2:00:00 PM

Re: F31GM151850-02

Dear Kirk, Melinda,

As Business Official for the above referenced award (PI HANNAH MARKOVIC), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: fbm5@uw.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:57:00 PM

Re: F31GM155953-01

Dear Fernando,

I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: odixit@health.ucsd.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM068524-22

Dear Oolka Dixit,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Shannon.Schechter@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM081266-17

Dear Schechter, Shannon,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Barbara.Gardner@tufts.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM133314-06

Dear Gardner, Barbara,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: nseilhan@ucsc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM139185-05

Dear Seilhan, Nelson,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: uw-aor@u.washington.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: K99GM141364-02

Dear Rhodes, Carol,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Arabella.Teng@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: K99GM151521-02

Dear Teng, Arabella,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: heather.hostetler@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: K99GM154059-01A1

Dear Hostetler, Heather,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: awards@umn.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: K99GM157491-01

Dear Thomas, Danielle,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: olsoje@ohsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM150451-02

Dear Olsen, Jennie,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Institutional Research and Academic Career Development Award (IRACDA)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Jeffrey.Schieder@buffalo.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM154101-02

Dear Schieder, Jeffrey,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research With Activities Related to Diversity (ReWARD) (R01)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: clarissa@udel.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R00GM143573-04

Dear Clarissa Roth,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: researchadmin@ucsd.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R00GM145970-03

Dear Michael Kusiak,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: aor@hawaii.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R00GM151640-02

Dear Diana Nettleton,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: anita.yip2@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM138700-05

Dear Anita Yip,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: jms1148@research.rutgers.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM151687-02

Dear Samolewicz, Justin Mark,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Jeffrey.Schieder@buffalo.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM154101-02

Dear Schieder, Jeffrey,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research With Activities Related to Diversity (ReWARD) (R01)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: waters@umbc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM154212-02

Dear Waters, Deborah,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research With Activities Related to Diversity (ReWARD) (R01)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: renuka.sippy@ucsf.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM144250-04

Dear Ms. Sippy, Renuka,

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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: baegan@rsp.wisc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM144251-04

Dear Brenda Egan,

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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: fvanderv@uoregon.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM152322-03

Dear FRANCES VANDERVOORT,

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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: preaward@rsp.wisc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: R01GM155840-01

Dear EGAN, BRENDA A,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01)** 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.

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If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: grants@tcnj.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM154615-01

Dear Heather Mayen,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: vchsgrants@health.ucsd.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM149445-02

Dear Anastasia Hendry,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Bigbie, Stacy
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM152941-02

Dear Stacy Catanach,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Leading Equity and Diveristy in the Medical Scientist Training Program (LEAD MSTP)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: maria.reyes@csulb.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM138075-04

Dear Maria Reyes,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Doctorate** 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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: CA737@rutgers.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM140951-04

Dear Timothy Kirby,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: candymoo@sfsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM142515-04

Dear Candy Mou,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Doctorate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ospa@umbc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM144876-03

Dear Deborah Waters,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ORS-AORContact@lists.hawaii.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM141986-04

Dear Sharleen Andreshak,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Kayla.Gundrum@nau.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM142618-04

Dear Kayla Gundrum,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: preaward@albany.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM145391-02

Dear Christine McCrary,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: jbonk@unr.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM145539-03

Dear JENNIFER ANN BONK,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sdsurfawards@sdsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM149430-02

Dear Jennie Amison,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Access to Research Careers (MARC)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sgartner@calpoly.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM154620-01

Dear Susanne Gartner,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ras@nmsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:15:00 PM

Re: GM148394-02

Dear Ms. Alisha A. Giron,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Graduate Research Training Initiative for Student Enhancement (G-RISE)** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: ras@nmsu.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM147348-02

Dear Alisha A. Giron,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: kchoi@pdx.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:14:00 PM

Re: GM147664-03

Dear Kathleen Choi,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Bridges to the Baccalaureate** 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.

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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

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: sponsoredprograms@unc.edu
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:51:00 PM

Re: UE5GM157254-01

Dear Jones, Nathan,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Advancing Research Careers (ARC)** 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.

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If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

National Institutes of Health
Office of Extramural Research

March 10, 2025

Angela V. Olinto, Ph.D.
Provost, Columbia University
Email: provost@columbia.edu

Dear Dr. Olinto:

NIH is hereby providing notice that funding for the projects in the attached spreadsheet will be terminated pursuant to the National Institutes of Health ("NIH") Grants Policy Statement (GPS),[1] and 2 C.F.R. § 200.340(a)(4).

As reflected in the Notices of Award for the most recent budget period of these projects, the NIH Grants Policy Statement is incorporated as a term and condition of award. The GPS "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[2] According to the GPS, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[3] At the time the Notices of Award were issued for the most recent budget period, 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."

These awards no longer effectuate 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.

NIH is responsible for ensuring that its limited resources are appropriately allocated. NIH policy is that grant dollars should support institutions that foster safe, equal, and healthy working and learning conditions conducive to high-quality research and free inquiry[4]—and should not subsidize institutions that are not built on American values of free speech, mutual respect, and open debate. In this vein, NIH is aware of recent events at Columbia University involving antisemitic action that suggest the institution has a disturbing lack of concern for the safety and wellbeing of Jewish students. Columbia's ongoing inaction in the face of repeated and severe harassment and targeting of Jewish students has ground day-to-day campus operations to a halt, deprived Jewish students of learning and research opportunities to which they are entitled, and brought shame upon the University and our nation as a whole. Supporting research in such an

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] NIH GPS, Section 3.
[3] *Id.* at Section 8.5.2.
[4] NIH GPS, Section 4.

environment is plainly inconsistent with NIH's priorities and raison d'etre of funding and championing the very best American research and educational institutions.

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,"[5] no corrective action is possible here. The actions described above are incompatible with agency priorities, and no modification of the projects could align the projects with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[6] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 200.344. 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*.[7]

Administrative Appeal

You may object and provide information and documentation challenging these terminations. NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[8]

You must submit a request for such review to Director Memoli no later than 30 days after this letter 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.[9]

The request for review must include a copy of this decision, 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.[10]

Sincerely,

Michelle G. Bulls
Director, Office Policy for Extramural Administration
Chief Grants Management Officer - National Institutes of Health
Email: michelle.bulls@nih.gov

cc:
William Berger, Assistant Vice President for Sponsored Projects Administration, Columbia University

[5] NIH GPS, Section 8.5.2.
[6] *See* 2 C.F.R. § 200.343.
[7] 2 C.F.R. § 200.341(c).
[8] See 42 C.F.R. Part 50, Subpart D.
[9] *Id.* § 50.406(a).
[10] *Id.* § 50.406(b).

From: Memoli, Matthew (NIH/OD) [E]
To: Bundesen, Liza (NIH/OD) [E]
Cc: Burklow, John (NIH/OD) [E]
Subject: NOFOS that need to come down
Date: Saturday, February 22, 2025 12:01:32 PM

Hi Liza,

I was sent a list of NOFOs to review that are still up. After my review I have determined these NOFOs in their current form have issues that cause them to not be properly directed at current NIH priorities. Please take these NOFOs down. Some of the projects my be reconsidered after they are modified to address current priorities and definitions.

https://grants.nih.gov/grants/guide/pa-files/PAR-23-112.html
https://grants.nih.gov/grants/guide/pa-files/PAR-22-145.html
https://grants.nih.gov/grants/guide/pa-files/PAR-23-309.html
https://grants.nih.gov/grants/guide/pa-files/PAR-23-292.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-077.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-109.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-157.html
https://grants.nih.gov/grants/guide/pa-files/PAR-24-158.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-098.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-201.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-237.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-240.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-241.html
https://grants.nih.gov/grants/guide/pa-files/PAR-25-317.html
https://grants.nih.gov/grants/guide/pa-files/PAR-26-001.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-003.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-NR-25-004.html
https://grants.nih.gov/grants/guide/rfa-files/RFA-MD-24-005.html

Thank you,
Matt

Matthew J. Memoli, MD, MS
Acting Director, NIH

Get Outlook for Mac

From: Memoli, Matthew (NIH/OD) [E]
To: Riley, Rachel (OS/ASA); Bulls, Michelle G. (NIH/OD) [E]
Subject: Re: Shortlist of SGM for Tonight
Date: Tuesday, March 11, 2025 9:49:35 PM

All of these grants can be terminated for being unaligned with current NIH /HHS priorities.

Matt

Get Outlook for Mac

From: Riley, Rachel (OS/ASA) <Rachel.Riley@hhs.gov>
Date: Tuesday, March 11, 2025 at 9:43 PM
To: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>, Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Subject: Shortlist of SGM for Tonight

Dr. Memoli –

Please see a short list below/attached; I have sent you 6 in case you find an issue with any one. If you are comfortable, the wonderful @Bulls, Michelle G. (NIH/OD) [E] will work to action tonight:

I will then get you an updated combined list for tomorrow!

Thanks,
Rachel

Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

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, 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.

Likewise, 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 either.

For these reasons and pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371–373),[1] the Director of NIH hereby directs:

> NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025

Matthew J. Memoli, M.D.
Acting Director of NIH

[1] To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

From: Bundesen, Liza (NIH/OD) [E]
To: Kosub, David (NIH/OD) [E]; Roman, Laurie (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Faenson, Inna (NIH/OD) [E]; Corbett, Dawn (NIH/OD) [E]; Boone, Ericka (NIH/OD) [E]
Cc: Jacobs, Anna (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Joshi, Pritty (NIH/OD) [E]
Subject: URGENT - FW: Memo on NIH priorities
Date: Friday, February 21, 2025 4:19:52 PM
Attachments: 2695_001.pdf

Hi all,

I'm very sorry to once again be sharing an urgent task on a Friday afternoon (I've already talked to David), but **today**, we have to pull down all of the NOFOs that we previously pulled down and put back up (DEI, gender ideology, environmental justice, etc). The attached memo from the Acting NIH Director provides this directive. I understand that Matt Memoli discussed this with OGC.

There are other actions that we will need to take to address this memo, but we can discuss those at a calmer pace on Monday.

I have confirmation that this memo can be shared with other OER staff, and I'm sending to this group now because I think you have the most immediate need to know. Please note that the memo is not to be distributed outside of OER at this time. I will think through how to notify the ICs.

I appreciate you all.

Liza

From: Memoli, Matthew (NIH/OD) [E] <matthew.memoli@nih.gov>
Sent: Friday, February 21, 2025 2:55 PM
To: Bundesen, Liza (NIH/OD) [E] <lbundese@mail.nih.gov>; Johnson, Alfred (NIH/OD) [E] <johnsoa1@mail.nih.gov>; Schor, Nina (NIH/OD) [E] <nina.schor@nih.gov>
Subject: Memo on NIH priorities

Hello,

After working with OGC we determined it was possible to set priorities at an NIH level, which now allows us to proceed with the process of making sure our programs are meeting these goals. I will talk with you individually about the plan of action.

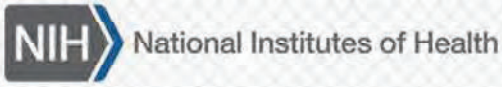
Thanks,
Matt

--
Matthew J. Memoli, MD, MS
Acting Director, National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
matthew.memoli@nih.gov

NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH



APRIL 2024

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.

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.

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

- 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.

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# F31GM151838
Federal Award Date
06/03/2025

Recipient Information

1. Recipient Name
THE REGENTS OF THE UNIVERSITY OF COLORADO
3100 MARINE ST
STE 481 572 UCB
BOULDER, CO 80309

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1846000555A2

4. Employer Identification Number (EIN)
846000555

5. Data Universal Numbering System (DUNS)
007431505

6. Recipient's Unique Entity Identifier
SPVKK1RC2MZ3

7. Project Director or Principal Investigator
Dominique Ramirez, BS

dora1300@colorado.edu
(303)-735-7860

8. Authorized Official
Meredith Swanson

Federal Agency Information

9. Awarding Agency Contact Information
ILENE GLASSMAN
Grants Management Specialist
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
glassmai@mail.nih.gov
301-594-4648

10. Program Official Contact Information
Joyce Chin-chin ng Stamm

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
joyce.stamm@nih.gov
(301) 827-5542

Federal Award Information

11. Award Number
1F31GM151838-01A1

12. Unique Federal Award Identification Number (FAIN)
F31GM151838

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Understanding the role of coiled-coil domains in regulating liquid-liquid phase separation of protein assemblies in cell division

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2024 **– End Date** 03/31/2025	
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	$41,984
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$41,984
26. Project Period Start Date 04/01/2024 **– End Date** 03/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$41,984

28. Authorized Treatment of Program Income

29. Grants Management Officer - Signature
Justin Rosenzweig

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: 6/5/2025 11:48 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 1F31GM151838-01A1 REVISED

Principal Investigator(s):
Dominique Ramirez, BS

Award e-mailed to: ocg@colorado.edu

Fellow's e-mail:
Dominique Ramirez dora1300@colorado.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF COLORADO 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 Of General Medical Sciences of the National Institutes of Health under Award Number F31GM151838. 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,

Justin Rosenzweig
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Institutional Allowance	$4,750
Other	$9,010
Stipends	$28,224

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/5/2025 11:48 AM

Federal Direct Costs	$41,984
Total Award	$41,984
Total Amount of Federal Funds Authorized (Federal Share)	$41,984
TOTAL FEDERAL AWARD AMOUNT	$41,984
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$41,984	$41,984

Fiscal Information:

Payment System Identifier:	1846000555A2
Document Number:	FGM151838A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
GM	8472202	$41,984

NIH Administrative Data:
PCC: T131SJ / **OC:** 41010 / **Released:** 2025-06-02
Award Processed: 06/05/2025 11:48:58 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1F31GM151838-01A1 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 – 1F31GM151838-01A1 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: 6/5/2025 11:48 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 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) F31GM151838. 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 Activation Notice (PHS 416-5) must be submitted to the NIH awarding office as of the day the fellow begins training. Submission of a Payback Agreement form is also required for postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. A payback agreement does not apply to predoctoral support. The applicable forms should be submitted to the awarding component at the following address:

Grants and Council Operations
NIH/NIGMS
45 Center Drive, MSC 6200
Building 45, Room 2AS.55
Bethesda, MD 208926200

The Activation Notice and Payback Agreement forms are available at the following websites:
http://grants1.nih.gov/grants/funding/416/phs416-5.pdf and
http://grants1.nih.gov/grants/funding/416/phs6031.pdf

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.

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 1F31GM151838-01A1 REVISED

Effective with this Notice of Award, this project is terminated. 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate, UNIVERSITY OF COLORADO may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 **60** days (non-human subjects and animals) **120** days (human subjects and animals) after the end of this project.

This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to Dr. Jon Lorsch, Director, NIGMS at nigmsreconsiderations@nigms.nih.gov.

TERMS AND CONDITIONS FROM THE PREVIOUS AWARD

Funds are provided in this revised award to support stipend and other budgetary levels in accordance with NIH Guide Notices NOT-OD-24-104 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html) and NOT-OD-24-116 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-116.html).

TERMS AND CONDITIONS FROM THE PREVIOUS AWARD

1. This fellowship cannot be activated prior to the federal award date cited on page 1 of this Notice of Award (or during the period from October 1 through November 15 if this award is issued after April 1). An Activation Notice (PHS 416-5) must be submitted before funding can be disbursed. Fellows who have received less than 12 months prior Kirschstein-NRSA postdoctoral support must complete a Payback Agreement (PHS 6031). These forms are available at: http://grants.nih.gov/grants/forms.htm. Completed Adobe PDF form(s) with digital signatures must be emailed from an Authorized Organization Representative to the Grants Management Specialist named in Section 9 ("Awarding Agency Contact Information") of the Notice of Award.

The sponsor for this fellowship award is Dr. Michael Shirts.

If the fellow is unable to complete the recommended length of support, Termination documentation must be submitted electronically via the xTrain Commons module within 30 days of the fellow's termination. In accord with the NIH Grants Policy Statement, "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."

2. Funds are provided in this award to support stipend and other budgetary levels in accordance with NIH Guide Notice NOT-OD-23-076 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-076.html).

3. The tuition/fees and institutional allowance have been awarded in accord with NIH Guide Notice NOT-OD-10-073, published March 24, 2010. This Notice can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-073.html. Tuition calculations were based on the amount of tuition and fees provided in the competing grant application. These funds are restricted solely for this purpose and may not be rebudgeted.

4. As appropriate, the awardee is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.

NIGMS' OFFICIAL WEBSITE

For more information, http://www.nigms.nih.gov

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1F31GM151838-01A1 REVISED

INSTITUTION: UNIVERSITY OF COLORADO

Budget	Year 1
Institutional Allowance	$4,750
Other	$9,010
Stipends	$28,224
TOTAL FEDERAL DC	$41,984
TOTAL FEDERAL F&A	$0
TOTAL COST	$41,984

Version: 25 - 2/15/2024 9:51 AM | Generated on: 6/5/2025 11:48 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# F31MD020261
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE
1608 4TH ST STE 201
BERKELEY, CA 94710

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1946002123A1

4. Employer Identification Number (EIN)
946002123

5. Data Universal Numbering System (DUNS)
124726725

6. Recipient's Unique Entity Identifier
GS3YEVSS12N6

7. Project Director or Principal Investigator
Larissa Benjamin, MPH

laribenj@berkeley.edu
248/935-4755

8. Authorized Official
EB Thorpe

Federal Agency Information

9. Awarding Agency Contact Information
Chantell Stevenson-Brown
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
Chantell.Stevenson-brown@nih.gov
(301) 402-1366

10. Program Official Contact Information
Nancy Lynne Jones
Health Scientist Administrator
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
jonesna@mail.nih.gov
301-594-8945

Federal Award Information

11. Award Number
1F31MD020261-01

12. Unique Federal Award Identification Number (FAIN)
F31MD020261

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Understanding the Macrosocial Drivers of Cardiovascular Health in the Rural South

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 11/01/2024 **– End Date** 10/31/2025	
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	$45,965
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$45,965
26. Project Period Start Date 11/01/2024 **– End Date** 10/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$45,965

28. Authorized Treatment of Program Income

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: 4/30/2025 12:16 AM

Notice of Research Fellowship Award

NATIONAL RESEARCH SERVICE AWARD
Department of Heath and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 1F31MD020261-01 REVISED

Principal Investigator(s):
Larissa Benjamin, MPH

Award e-mailed to: spoawards@berkeley.edu

Fellow's e-mail:
Larissa Benjamin laribenj@berkeley.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA BERKELEY 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 Minority Health And Health Disparities of the National Institutes of Health under Award Number F31MD020261. 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)

Institutional Allowance	$4,750
Other	$12,991

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:16 AM

Stipends	$28,224
Federal Direct Costs	$45,965
Total Award	$45,965
Total Amount of Federal Funds Authorized (Federal Share)	$45,965
TOTAL FEDERAL AWARD AMOUNT	$45,965
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$45,965	$45,965

Fiscal Information:

Payment System Identifier:	1946002123A1
Document Number:	FMD020261A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
MD	8020239	$45,965

NIH Administrative Data:
PCC: CPS07 / **OC:** 41010 / **Released:** 2025-04-29
Award Processed: 04/30/2025 00:16:41 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1F31MD020261-01 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 – 1F31MD020261-01 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:16 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) F31MD020261. 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 Activation Notice (PHS 416-5) must be submitted to the NIH awarding office as of the day the fellow begins training. Submission of a Payback Agreement form is also required for postdoctoral fellows in their first 12 months of Kirschstein-NRSA postdoctoral support. A payback agreement does not apply to predoctoral support. The applicable forms should be submitted to the awarding component at the following address:

National Institute on Minority Health and Health Disparities
Extramural Activities MSC 5465
6707 Democracy Blvd. Suite 800
Bethesda, MD 20892
Bethesda, MD 20892

The Activation Notice and Payback Agreement forms are available at the following websites:
http://grants1.nih.gov/grants/funding/416/phs416-5.pdf and
http://grants1.nih.gov/grants/funding/416/phs6031.pdf

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 – MD SPECIFIC AWARD CONDITIONS – 1F31MD020261-01 REVISED

It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed. University of California Berkeley 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.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award reflects the NIMHD's receipt and acceptance of Other Support dated 12/12/2024.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 9/17/2024 ALSO APPLY TO THIS AWARD:

RESTRICTION: This award may not continue beyond the completion of all doctoral degree requirements. Support for this fellowship will end upon the receipt of a doctoral degree. No funds may be drawn down after the receipt of a doctoral degree. A termination notice must be submitted to the National Institutes of Health upon receipt of a doctoral degree.

REQUIREMENT: This award is subject to the conditions set forth in PA-23-272, Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31), 08/17/2023, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PA-23-271.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT To activate this fellowship, complete NRSA Individual Fellowship Activation Notice (form PHS 416-5) http://grants.nih.gov/grants/funding/416/phs416-5.pdf prior to activation date.

INFORMATION Should this fellowship terminate early, a Termination Notice (PHS 416-7) must be submitted. The completed form must be submitted immediately following the termination of support. Per NIH Policy, submit the Termination Notice via xTrain (era Commons) http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1F31MD020261-01 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA BERKELEY

Budget	Year 1
Institutional Allowance	$4,750
Other	$12,991
Stipends	$28,224
TOTAL FEDERAL DC	$45,965
TOTAL FEDERAL F&A	$0
TOTAL COST	$45,965

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:16 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# K99GM154061
Federal Award Date
05/19/2025

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
Rene Marlene Arvola, PHD

arvola.1@osu.edu
614-292-2640

8. Authorized Official
Janet Tobler

Federal Agency Information

9. Awarding Agency Contact Information
Susan F. South

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
southsf@mail.nih.gov
301-594-4495

10. Program Official Contact Information
Kalynda K Stokes

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
kalynda.stokes@nih.gov
301-594-6450

Federal Award Information

11. Award Number
1K99GM154061-01

12. Unique Federal Award Identification Number (FAIN)
K99GM154061

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Investigating UPF3 paralog function in Nonsense-Mediated mRNA Decay and Genetic Compensation

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/05/2024 **– End Date** 03/31/2025	
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	$110,151
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$110,151
26. Project Period Start Date 04/05/2024 **– End Date** 03/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$172,226

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Justin Rosenzweig

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: 5/19/2025 4:28 PM

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Notice of Award

CAREER TRANSITION AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 1K99GM154061-01 REVISED

Principal Investigator(s):
Rene Marlene Arvola, 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 General Medical Sciences of the National Institutes of Health under Award Number K99GM154061. 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,

Justin Rosenzweig
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$61,572

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/19/2025 4:28 PM

Fringe Benefits	$21,920
Personnel Costs (Subtotal)	$83,492
Materials & Supplies	$5,000
Travel	$2,000
Other	$10,000
Publication Costs	$1,500
Federal Direct Costs	$101,992
Federal F&A Costs	$8,159
Approved Budget	$110,151
Total Amount of Federal Funds Authorized (Federal Share)	$110,151
TOTAL FEDERAL AWARD AMOUNT	$110,151
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$110,151	$110,151

Fiscal Information:
Payment System Identifier: 1316025986A1
Document Number: KGM154061A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
GM	8472199	$110,151

NIH Administrative Data:
PCC: T256KK / **OC**: 41033 / **Released**: 05/16/2025
Award Processed: 05/19/2025 04:28:03 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K99GM154061-01 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 – 1K99GM154061-01 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: 5/19/2025 4:28 PM

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) K99GM154061. 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.

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

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/19/2025 4:28 PM

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 1K99GM154061-01 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.

Effective with this Notice of Award, this project is terminated. 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 ICO's, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Therefore, no additional funding will be awarded for this project, and all future years have been removed. If appropriate,Ohio State University may request funds to support patient safety and animal welfare to support an orderly phaseout of the project.

Requests to draw down funds must be submitted to OPERAFFRInquiries@od.nih.gov for prior approval, before submitting in the HHS Payment Management System. The request must include the drawdown amount, justification, and appropriate supporting documentation. Approval will only be provided for costs incurred prior to the date of termination (with proof of the date), or costs for patient safety or animal welfare, in support of an orderly phaseout 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 phaseout 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 60 days (non-human subjects and animals) 120 days (human subjects and animals) after the end of this project.

This action aligns with Termination - 2 C.F.R. § 200.340 (a)(4). This is a final determination. If you wish to seek a reconsideration because you object to the ICO's termination, please submit a reconsideration request to Dr. Jon Lorsch, Director, NIGMS.

TERMS AND CONDITIONS FROM PREVIOUS AWARD:

1. This award is subject to the conditions set forth in PAR-21-271, **Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC)** Postdoctoral Career Transition Award to Promote Diversity, which are hereby incorporated by reference as special terms and conditions of this award. Copies of this PA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PAR-21-271.html

Additional information on the MOSAIC Programs may be found at the following internet address: https://www.nigms.nih.gov/training/careerdev/Pages/MOSAIC.aspx

2. IMPORTANT: MOSAIC K99/R00 scholars will be part of organized scientific cohorts coordinated by MOSAIC Institutionally-Focused Research Education Award to Promote Diversity (UE5) grantees. The PI and their primary mentor are expected to participate in mentoring, networking, and professional development activities by the **American Society for Biochemistry and Molecular Biology** (ASBMB: https://www.asbmb.org/diversity/mosaic).

3. Since the principal purpose of this award is to transition the principal investigator to an independent investigator, no request to change the principal investigator will be considered.

4. A progress report for the -02 year of support should be submitted through the NIH Commons no later than 45 days before the end of the -01 year and must incorporate all application sections noted in the Program Announcement.

5. In the event the transition to the R00 phase occurs prior to the current project period end date of 03/31/2026, this K99 award level may be adjusted accordingly.

6. As appropriate, the grant recipient is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any

changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.

SECTION V - NIGMS CONTACTS

The NIGMS WWW home page is at http://www.nigms.nih.gov

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: 1K99GM154061-01 REVISED

INSTITUTION: OHIO STATE UNIVERSITY

Budget	Year 1
Salaries and Wages	$61,572
Fringe Benefits	$21,920
Personnel Costs (Subtotal)	$83,492
Materials & Supplies	$5,000
Travel	$2,000
Other	$10,000
Publication Costs	$1,500
TOTAL FEDERAL DC	$101,992
TOTAL FEDERAL F&A	$8,159
TOTAL COST	$110,151

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	8%
F&A Cost Base 1	$101,992
F&A Costs 1	$8,159

Version: 25 - 2/15/2024 9:51 AM | Generated on: 5/19/2025 4:28 PM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# K99MD019292
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF SOUTHERN CALIFORNIA
3720 S FLOWER ST FL 3
LOS ANGELES, CA 90033

2. Congressional District of Recipient
37

3. Payment System Identifier (ID)
1951642394A1

4. Employer Identification Number (EIN)
951642394

5. Data Universal Numbering System (DUNS)
072933393

6. Recipient's Unique Entity Identifier
G88KLJR3KYT5

7. Project Director or Principal Investigator
Samantha Garcia, PHD

sg_196@usc.edu
323-865-6013

8. Authorized Official
Ms. Lillian Ann Rivera

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
OLGA MARINA Herren
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
Olga.Herren@nih.gov
301-402-4492

Federal Award Information

11. Award Number
1K99MD019292-01

12. Unique Federal Award Identification Number (FAIN)
K99MD019292

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A Multilevel Social Capital Approach to Address Cervical Cancer Screening and Follow Up Delays among Latinas in Safety-Net Settings

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/03/2024 **– End Date** 04/30/2025	
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	$109,768
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$109,768
26. Project Period Start Date 07/03/2024 **– End Date** 04/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$109,768

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: 4/30/2025 12:04 AM

Notice of Award

CAREER TRANSITION AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 1K99MD019292-01 REVISED

Principal Investigator(s):
Samantha Garcia, PHD

Award e-mailed to: uscaward@usc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF SOUTHERN CALIFORNIA 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 K99MD019292. 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: 4/30/2025 12:04 AM

Salaries and Wages	$71,758
Fringe Benefits	$17,581
Personnel Costs (Subtotal)	$89,339
Other	$12,298
Federal Direct Costs	$101,637
Federal F&A Costs	$8,131
Approved Budget	$109,768
Total Amount of Federal Funds Authorized (Federal Share)	$109,768
TOTAL FEDERAL AWARD AMOUNT	$109,768
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$109,768	$109,768

Fiscal Information:
Payment System Identifier: 1951642394A1
Document Number: KMD019292A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8055729	$50,000
MD	8476640	$59,768

NIH Administrative Data:
PCC: IBB04OH / **OC**: 41033 / **Released**: 04/29/2025
Award Processed: 04/30/2025 12:04:09 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K99MD019292-01 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 – 1K99MD019292-01 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-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

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) K99MD019292. 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.

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) National Institute On Minority Health And Health Disparities (NIMHD)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 1K99MD019292-01 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.

It is the policy of NIH not to prioritize research programs related to 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Therefore, no additional funding will be awarded for this project, and all future years have been removed. University of Southern California 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.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award adjusts the budget period end date to 4/30 due to the size of the estimated unobligated balance.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 8/27/2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award corrects the Common Accounting Number (CAN).

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 7/03/2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This award reflects support from the National Institute on Minority Health and Health Disparities (NIMHD) in the amount of $59,768 total costs and from the Office of Behavioral and Social Sciences Research (OBSSR) in the amount of $50,000 total costs.

REQUIREMENT This award is subject to the conditions set forth in PAR-21-271, Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 Independent Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 08/17/2021, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PAR-21-271.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: A complete application for the Independent Investigator Phase (R00) must be submitted to the NIMHD no later than 2 months prior to the K99 award's project period end date. As indicated in the Program Announcement for this mechanism, the applicant must demonstrate in the application that an independent tenure-track, full-time assistant professor position has been secured. Applicants are strongly encouraged to review the Program Announcement and discuss with the Program Official listed below, as early as possible, proposed transition plans.

Award of the R00 phase is not automatic. Applicants that are approved to transition will receive a Notice of Grant Award reflecting the new grant mechanism, the dollar amount, and the new recipient organization (if applicable). Applicants that are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This letter typically will be sent within 60 days of receipt of the R00 application.

Since the principal purpose of this award is to transition the principal investigator to an independent investigator, no request to change the principal investigator will be considered.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

A Federal Financial Report (SF-425) must be submitted within 120 days of the end date of the K99 phase.

In addition, if the R00 phase is NOT funded, grant closeout documents consisting of a Final Invention Statement (HHS 568), and a final RPPR must also be submitted within 120 days of the expiration date. Closeout documents should be submitted through the NIH Commons available at https://commons.era.nih.gov/commons/. Additional information is available at the Commons Homepage or by contacting the eRA Helpdesk at: commons@od.nih.gov or (866) 504-9552.

REQUIREMENT: Since the principal purpose of this award is to transition the principal investigator to an independent investigator, no request to change the principal investigator will be considered.

REQUIREMENT: Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9 person-months) to their career development and research during the mentored phase.

RESTRICTION: National Institutes of Health (NIH) research or training grant funds (both direct costs and associated facilities and administrative costs) released as a result of this Career Development Award may not be retained by the awardee institution without written prior approval of the NIH awarding unit.

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: 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 1st.

INFORMATION: Although the budget period start date for this award is July 3rd, this award includes funds for 12 months of support. Future year budget periods will cycle on February 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 institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

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: 1K99MD019292-01 REVISED

INSTITUTION: UNIVERSITY OF SOUTHERN CALIFORNIA

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

Budget	Year 1
Salaries and Wages	$71,758
Fringe Benefits	$17,581
Personnel Costs (Subtotal)	$89,339
Other	$12,298
TOTAL FEDERAL DC	$101,637
TOTAL FEDERAL F&A	$8,131
TOTAL COST	$109,768

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	8%
F&A Cost Base 1	$101,637
F&A Costs 1	$8,131

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R61HD117134
Federal Award Date
03/14/2025

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
617-466-9262

8. Authorized Official
Cary Williams

Federal Agency Information

9. Awarding Agency Contact Information
Yvonne C. Talley
Grants Management Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
talleyy@mail.nih.gov
301-496-7432

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
1R61HD117134-01

12. Unique Federal Award Identification Number (FAIN)
R61HD117134

13. Statutory Authority
42 USC 241 42 CFR PART 52

14. Federal Award Project Title
Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/26/2024 **– End Date** 03/12/2025	
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	$838,837
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$838,837
26. Project Period Start Date 08/26/2024 **– End Date** 03/12/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$838,837

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:25 - 2/15/2024 9:51 AM | Generated on: 3/15/2025 12:09 AM

Notice of Award

Phase 1 Exploratory/Developmental Grant
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R61HD117134-01 REVISED

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: research_admin@hphci.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R61HD117134. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/15/2025 12:09 AM

Salaries and Wages	$140,347
Fringe Benefits	$41,823
Personnel Costs (Subtotal)	$182,170
Consultant Services	$5,000
Travel	$6,500
Subawards/Consortium/Contractual Costs	$500,845
Federal Direct Costs	$694,515
Federal F&A Costs	$144,322
Approved Budget	$838,837
Total Amount of Federal Funds Authorized (Federal Share)	$838,837
TOTAL FEDERAL AWARD AMOUNT	$838,837
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$838,837	$838,837

Fiscal Information:
Payment System Identifier: 1042452600A1
Document Number: RHD117134A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
OD	8055729	$838,837

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41021 / **Released**: 03/14/2025
Award Processed: 03/15/2025 12:09:47 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD117134-01 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 – 1R61HD117134-01 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: 3/15/2025 12:09 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).

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) R61HD117134. 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: 3/15/2025 12:09 AM

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 – HD SPECIFIC AWARD CONDITIONS – 1R61HD117134-01 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: This revised award terminates the budget, and the project end dates to 03/12/2025.

It is the policy of NIH not to prioritize Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/15/2025 12:09 AM

programs. Therefore, this project is terminated. HARVARD PILGRIM HEALTH CARE, INC., may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered.

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. Â§ 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.

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: 1R61HD117134-01 REVISED

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 1
Salaries and Wages	$140,347
Fringe Benefits	$41,823
Personnel Costs (Subtotal)	$182,170
Consultant Services	$5,000
Travel	$6,500
Subawards/Consortium/Contractual Costs	$500,845
TOTAL FEDERAL DC	$694,515
TOTAL FEDERAL F&A	$144,322
TOTAL COST	$838,837

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	66%
F&A Cost Base 1	$218,670
F&A Costs 1	$144,322

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/15/2025 12:09 AM

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Linde, Emily (NIH/NIAID) [E]
Subject: FW: Grant Termination Notification
Date: Monday, March 24, 2025 8:34:28 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Monday, March 24, 2025 3:52 PM
To: gavin.rynne@ucsf.edu
Subject: Grant Termination Notification

3/24/2025

Rynne, Gavin
University Of California, San Francisco
gavin.rynne@ucsf.edu

Dear Rynne, Gavin:

Effective with the date of this letter, funding for Project Number 1U19AI171110-01 is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 5/16/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

04/07/2025

Yale University
100 Church Street South
New Haven, CT 06519

Sharon E. Murphy:

Funding for Project Number 1UC2CA293786-01 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 09/04/2024, 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

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# T32GM135742
Federal Award Date
04/24/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA SANTA CRUZ
1156 HIGH ST
SANTA CRUZ, CA 95064

2. Congressional District of Recipient
19

3. Payment System Identifier (ID)
1941539563A1

4. Employer Identification Number (EIN)
941539563

5. Data Universal Numbering System (DUNS)
125084723

6. Recipient's Unique Entity Identifier
VXUFPE4MCZH5

7. Project Director or Principal Investigator
Melissa S Jurica, PHD
Professor
mjurica@ucsc.edu
831-459-4427

8. Authorized Official
Kevin Hagedorn

Federal Agency Information

9. Awarding Agency Contact Information
Jun Moy

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
jun.moy@nih.gov
(301) 594-2761

10. Program Official Contact Information
Jeremy Colin Mcintyre

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
jeremy.mcintyre@nih.gov
(301) 827-5011

Federal Award Information

11. Award Number
2T32GM135742-06

12. Unique Federal Award Identification Number (FAIN)
T32GM135742

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
UCSC IMSD

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2025 **– End Date** 04/30/2025	
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	$328,320
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$328,320
26. Project Period Start Date 02/01/2020 **– End Date** 04/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$328,320

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Julie Peoples Orlando

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: 4/25/2025 12:14 AM

Notice of Award

NATIONAL RESEARCH SERVICE AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 2T32GM135742-06 REVISED

Principal Investigator(s):
Melissa S Jurica, PHD

Award e-mailed to: ospdocs@ucsc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA SANTA CRUZ 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 Of General Medical Sciences of the National Institutes of Health under Award Number T32GM135742. 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,

Julie Peoples Orlando
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Childcare Costs	$18,000
Stipends	$169,344
Tuition & Fees	$56,148

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/25/2025 12:14 AM

Trainee Travel	$6,000
Training related Expenses	$60,000
Federal Direct Costs	$309,492
Federal F&A Costs	$18,828
Approved Budget	$328,320
Total Amount of Federal Funds Authorized (Federal Share)	$328,320
TOTAL FEDERAL AWARD AMOUNT	$328,320
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)								
	THIS AWARD				**CUMULATIVE TOTALS**			
YR	**Total**	**Pre**	**Post**	**Short Term**	**Cumulative Total**	**Pre**	**Post**	**Short Term**
6	$328,320	6			$328,320	6		

Fiscal Information:
Payment System Identifier: 1941539563A1
Document Number: TGM135742B
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025
GM	8039713	$328,320

NIH Administrative Data:
PCC: T417JM / **OC**: 41011 / **Released**: 04/24/2025
Award Processed: 04/25/2025 12:14:33 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2T32GM135742-06 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 – 2T32GM135742-06 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This 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) T32GM135742. 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.

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.

Childcare Costs:
This award includes childcare costs of $3,000 per full-time predoctoral or postdoctoral trainee. These funds are restricted and may not be used for any other purpose.

Treatment of Program Income:
Additional Costs

Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government, and Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 U.S.C. § 3729, and/or criminal liability, including under 18 U.S.C. §§ 287 and 1001.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/25/2025 12:14 AM

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 2T32GM135742-06 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.

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. It is the policy of NIH not to prioritize such research programs.

Therefore, no additional funding will be awarded for this project, and all future years have been removed. The University of California, Santa Cruz, may request funds to support animal/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.

TERMS AND CONDITIONS FROM THE PREVIOUS AWARD

This award is issued with a restriction since the following documents have not been received by NIH:

- Trainee Termination Notices (PHS 416-7) for Sophie Grace Jimenez and Anthony Rodriguez Lemus.
- The year -04 FFR should be revised to more accurately reflect unliquidated obligations, or the grantee should explain why it does not need to be revised.

No trainee appointments to year -06 will be accepted and no award funds may be expended until the documents have been submitted and accepted. Once the documents are accepted, this award will be revised to rescind the restriction and trainee appointments may be made retroactive to the February 1, 2025 budget start date.

The FFR must be submitted through the Payment Management System (PMS) per NOT-OD-21-046.

In accordance with NIH Guide Notice NOT-OD-10-072, appointment and termination documentation for Kirschstein-NRSA predoctoral and postdoctoral institutional training grants must be submitted electronically via xTrain as of January 1, 2011 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html). Additional information on xTrain, as well as training and reference materials can be found on the xTrain website: https://era.nih.gov/help-tutorials/xtrain.

1. This grant must be administered in accordance with the guidelines and restrictions described in the **Initiative for Maximizing Student Development (IMSD) (T32) program announcement PAR-24-031** available at: https://grants.nih.gov/grants/guide/pa-files/PAR-

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/25/2025 12:14 AM

24-031.html. These guidelines are in addition to the standard Terms and Conditions referenced in Section III of this Notice of Award.

For more information on the Initiative for Maximizing Student Development (IMSD) (T32) program as well as answers to Frequently Asked Questions, please visit: https://www.nigms.nih.gov/training/IMSD

2. This award contains a lump sum that has been awarded under the category "TRAINING RELATED EXPENSES." These funds may be rebudgeted within applicable Public Health Service policies in order to meet the expenses in personnel, consultants, equipment, supplies, travel and other, unless the rebudgeting has been specifically prohibited in a previous Notice of Award.

3. Funds are provided in this award to support stipend and other budgetary levels in accordance with NIH Guide Notice NOT-OD-24-104 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html).
4. It is understood that no trainee will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate.

If any trainee undertakes a project that includes human subject research studies, these must conform to the NIH policies on the inclusion of women, minorities, and children in study populations.

5. This award includes funds to support 6 trainees (72 Trainee Months). The maximum number of trainees that may be appointed without the prior written approval of NIGMS staff is 12 (144 Trainee Months) if funds are available through rebudgeting.

6. Although future years include a recommended number of trainee positions, actual award levels are contingent upon availability of funds. In general, grantees should NOT expect an increase in the actual number of slots awarded in future years unless notified by institute program staff.

7. In accordance with NIH Guide Notice NOT-OD-10-072, appointment and termination documentation for Kirschstein-NRSA predoctoral and postdoctoral institutional training grants must be submitted electronically via xTrain as of January 1, 2011 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html). Additional information on xTrain, as well as training and reference materials can be found on the xTrain website: https://era.nih.gov/help-tutorials/xtrain.

IMPORTANT: Appointments must be filed prior to or at the time of each trainee's appointment. No stipend or other allowances may be paid until submission of the proper documentation. Terminations must be filed prior to or at the time of each trainee's termination of support. Failure to submit documentation may result in an expenditure disallowance or a delay in continued funding.

8. As appropriate, the grant recipient is required to follow the sharing plan(s) for unique research resources (i.e. Data, Model Organism, Genomic Data, or other) associated with this project and may not implement any changes to the plan(s) without the written prior approval of the National Institute of General Medical Sciences.

9. The next non-competing progress report for this grant is due on June 15, 2025.

10. 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

11. NIH policy requires the submission of an annual Federal Financial Report (FFR) 90 days after the end of the calendar quarter in which the budget period ends. The FFR must be submitted through the Payment Management System (PMS) per NOT-OD-21-046. **The grant recipient is reminded that acceptance of an FFR by the NIH Office of Policy for Extramural Research Administration (OPERA) does not authorize the carry forward or expenditure of any remaining unobligated balance. As stated in Section III of this Notice of Award, only the NIGMS Grants Management Officer (or their designee) can authorize the carry forward of unobligated balances. Expenditures utilizing any portion of a remaining unobligated balance without prior approval will be disallowed.**

NIGMS' OFFICIAL WEBSITE

For more information, http://www.nigms.nih.gov

Data Management and Sharing Policy: Not Applicable

As outlined in the Notice of Funding Opportunity, this project is not expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing does not apply. Any changes to the project that result in the generation of scientific data require NIH prior approval, and may require submission of a Data Management and Sharing Plan. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 2T32GM135742-06 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA SANTA CRUZ

Budget	Year 6
Childcare Costs	$18,000
Stipends	$169,344
Tuition & Fees	$56,148
Trainee Travel	$6,000
Training related Expenses	$60,000
TOTAL FEDERAL DC	$309,492
TOTAL FEDERAL F&A	$18,828
TOTAL COST	$328,320

Facilities and Administrative Costs	Year 6
F&A Cost Rate 1	8%
F&A Cost Base 1	$235,344
F&A Costs 1	$18,828

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# U24MD017250
Federal Award Date
03/23/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425
SAN FRANCISCO, CA 94103

2. Congressional District of Recipient
11

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
STUART A GANSKY, DRPH (Contact)
Professor
Stuart.Gansky@ucsf.edu
+1 415 502-8094

8. Authorized Official
Annie Gregory

Federal Agency Information

9. Awarding Agency Contact Information
Chantell Stevenson-Brown
Grants Management Specialist
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
Chantell.Stevenson-brown@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
3U24MD017250-04S1

12. Unique Federal Award Identification Number (FAIN)
U24MD017250

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
Research Coordinating Center to Reduce Disparities in Multiple Chronic Diseases (RCC RD-MCD)

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Supplement (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	$235,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$235,000
26. Project Period Start Date 09/24/2021 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$18,443,323

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: 3/25/2025 12:24 AM

Notice of Award

RESOURCE-RELATED COOPERATIVE AGREEMENT PROJECTS

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 3U24MD017250-04S1 REVISED

Principal Investigator(s):
Edwin Duncan Charlebois, PHD
STUART A GANSKY (contact), DRPH
Kim Felder Rhoads, MD

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 31 USC 6305 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 U24MD017250. 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

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

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$77,167
Fringe Benefits	$24,244
Personnel Costs (Subtotal)	$101,411
Consultant Services	$21,801
Materials & Supplies	$181
Travel	$18,324
Other	$1,575
Federal Direct Costs	$143,292
Federal F&A Costs	$91,708
Approved Budget	$235,000
Total Amount of Federal Funds Authorized (Federal Share)	$235,000
TOTAL FEDERAL AWARD AMOUNT	$235,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$235,000	$235,000

Fiscal Information:

Payment System Identifier:	1946036493A6
Document Number:	UMD017250A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
OD	8044257	$235,000

NIH Administrative Data:
PCC: CPS10NS / **OC**: 41028 / **Released**: 03/23/2025
Award Processed: 03/25/2025 12:24:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3U24MD017250-04S1 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 – 3U24MD017250-04S1 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.
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Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/25/2025 12:24 AM

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 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) U24MD017250. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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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: 3/25/2025 12:24 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 – MD SPECIFIC AWARD CONDITIONS – 3U24MD017250-04S1 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.

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

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

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 9/10/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is co-funded by the Office of Data Science Strategy (ODSS), Office of the Director, NIH to support the NAIRR ScHARe-HEAN Pilot Project and is subject to the conditions set forth in PA-20-272, Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional), NIH Guide to Grants and Contracts, which are hereby incorporated by reference as special terms and conditions of this award. These funds are restricted for this purpose and may not be expended for any other purpose without the written prior approval of the National Institute on Minority Health and Health Disparities.

Copies of this RFA may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html
Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."
Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html
Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

SPREADSHEET SUMMARY
AWARD NUMBER: 3U24MD017250-04S1 REVISED

INSTITUTION: The Regents of the UCSF

Budget	Year 4
Salaries and Wages	$77,167
Fringe Benefits	$24,244
Personnel Costs (Subtotal)	$101,411

Consultant Services	$21,801
Materials & Supplies	$181
Travel	$18,324
Other	$1,575
TOTAL FEDERAL DC	$143,292
TOTAL FEDERAL F&A	$91,708
TOTAL COST	$235,000

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	64%
F&A Cost Base 1	$143,293
F&A Costs 1	$91,708

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

Department of Health and Human Services **Notice of Award**
National Institutes of Health FAIN# R00MD016964
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES **Federal Award Date**
04/29/2025

Recipient Information

1. Recipient Name
NORTHWESTERN UNIVERSITY
633 CLARK ST
EVANSTON, IL 60208

2. Congressional District of Recipient
09

3. Payment System Identifier (ID)
1362167817A1

4. Employer Identification Number (EIN)
362167817

5. Data Universal Numbering System (DUNS)
005436803

6. Recipient's Unique Entity Identifier
KG76WYENL5K1

7. Project Director or Principal Investigator
Kynon Jade M Benjamin, PHD

jade.benjamin@libd.org
3172928067

8. Authorized Official
Rujuta Narurkar

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
Iman Martin

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
iman.martin@nih.gov
301-827-5814

Federal Award Information

11. Award Number
4R00MD016964-03

12. Unique Federal Award Identification Number (FAIN)
R00MD016964

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Comprehensive computational analysis of genetic and regulatory differences between individuals with African and European ancestries across four brain regions

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Extension with or without funds (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2024 **– End Date** 03/31/2025	
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	$249,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$249,000
26. Project Period Start Date 12/01/2021 **– End Date** 03/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$249,000

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: 4/30/2025 12:04 AM

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Notice of Award

RESEARCH TRANSITION AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 4R00MD016964-03 REVISED

Principal Investigator(s):
Kynon Jade M Benjamin, PHD

Award e-mailed to: OSR-Awards@northwestern.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 NORTHWESTERN UNIVERSITY CHICAGO 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 R00MD016964. 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: 4/30/2025 12:04 AM

Salaries and Wages	$42,000
Fringe Benefits	$11,550
Personnel Costs (Subtotal)	$53,550
Equipment	$135,320
Travel	$4,000
Other	$6,000
Publication Costs	$7,500
Federal Direct Costs	$206,370
Federal F&A Costs	$42,630
Approved Budget	$249,000
Total Amount of Federal Funds Authorized (Federal Share)	$249,000
TOTAL FEDERAL AWARD AMOUNT	$249,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$249,000	$249,000

Fiscal Information:
Payment System Identifier: 1362167817A1
Document Number: RMD016964B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MD	8472687	$249,000

NIH Administrative Data:
PCC: IBB01IM / **OC**: 41025 / **Released**: 04/29/2025
Award Processed: 04/30/2025 12:04:03 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 4R00MD016964-03 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 – 4R00MD016964-03 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 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) R00MD016964. 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: 4/30/2025 12:04 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 – MD SPECIFIC AWARD CONDITIONS – 4R00MD016964-03 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 research programs related to 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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Therefore, no additional funding will be awarded for this project, and all future years have been removed. Northwestern University 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.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award corrects the recipient's name from Lieber Institute, Inc. to Northwestern University and restores the funding to the original level.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 12/5//2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award deobligates the funds in order to promptly reissue the award to the correct recipient organization.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 8/24/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: The PI is required to devote no less than 75% of their full-time, 12-month professional effort to research (i.e., full-time for 9 person-months).

REQUIREMENT: This award is subject to the conditions set forth in PAR-19-343, Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/2020, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PA-19-343.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

INFORMATION MOSAIC K99/R00 scholars will be part of organized scientific cohorts coordinated by MOSAIC Institutionally-Focused Research Education Award to Promote Diversity (UE5) grantees. The PI and their primary mentor are expected to participate in mentoring, networking, and professional development activities by the American Society for Biochemistry and Molecular Biology (ASBMB: https://www.asbmb.org/diversity/mosaic), the American Society for Cell Biology (ASCB: https://www.ascb.org/career-development/ascb-mosaic-program-amp/) and the Association of American Medical Colleges (AAMC: https://www.aamc.org/what-we-do/mission-areas/medical-research/aamc-career-development-program-mosaic-scholars)

REQUIREMENT: The recipient is required to follow the data sharing plan included in the competing application and may not implement any changes in the plan without the written prior approval of NIMHD.

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).

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

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.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "**Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice,**" and NIH-OD-15-128, "**Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice.**"

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

SPREADSHEET SUMMARY
AWARD NUMBER: 4R00MD016964-03 REVISED

INSTITUTION: NORTHWESTERN UNIVERSITY CHICAGO

Budget	Year 3
Salaries and Wages	$42,000
Fringe Benefits	$11,550
Personnel Costs (Subtotal)	$53,550
Equipment	$135,320
Travel	$4,000
Other	$6,000
Publication Costs	$7,500
TOTAL FEDERAL DC	$206,370
TOTAL FEDERAL F&A	$42,630
TOTAL COST	$249,000

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	60%
F&A Cost Base 1	$71,050
F&A Costs 1	$42,630

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:04 AM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# K99MD018629
Federal Award Date
04/29/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE
1608 4TH ST STE 201
BERKELEY, CA 94710

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1946002123A1

4. Employer Identification Number (EIN)
946002123

5. Data Universal Numbering System (DUNS)
124726725

6. Recipient's Unique Entity Identifier
GS3YEVSS12N6

7. Project Director or Principal Investigator
Amanda Danielle Perez

adpc@berkeley.edu
510-643-1999

8. Authorized Official
Mr. Jason Cheung

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
Deborah Elizabeth Linares
Health Science Administrator
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
deborah.linares@nih.gov
301-402-1366

Federal Award Information

11. Award Number
5K99MD018629-02

12. Unique Federal Award Identification Number (FAIN)
K99MD018629

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Racism-related stress and birth outcomes among Latinas: New tools for maximizing conceptual and methodological validity

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 **– End Date** 04/30/2025	
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	$135,943
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$135,943
26. Project Period Start Date 08/02/2023 **– End Date** 04/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$267,851

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: 4/30/2025 12:05 AM

Notice of Award

CAREER TRANSITION AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5K99MD018629-02 REVISED

Principal Investigator(s):
Amanda Danielle Perez

Award e-mailed to: spoawards@berkeley.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA BERKELEY 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 K99MD018629. 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: 4/30/2025 12:05 AM

Salaries and Wages	$90,000
Fringe Benefits	$12,600
Personnel Costs (Subtotal)	$102,600
Travel	$7,473
Other	$15,800
Federal Direct Costs	$125,873
Federal F&A Costs	$10,070
Approved Budget	$135,943
Total Amount of Federal Funds Authorized (Federal Share)	$135,943
TOTAL FEDERAL AWARD AMOUNT	$135,943
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$135,943	$135,943

Fiscal Information:
Payment System Identifier: 1946002123A1
Document Number: KMD018629A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MD	8476640	$135,943

NIH Administrative Data:
PCC: IBB03DL / **OC**: 41035 / **Released**: 04/29/2025
Award Processed: 04/30/2025 12:05:12 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5K99MD018629-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5K99MD018629-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:05 AM

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) K99MD018629. 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: 4/30/2025 12:05 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 – MD SPECIFIC AWARD CONDITIONS – 5K99MD018629-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

It is the policy of NIH not to prioritize research programs related to 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, no additional funding will be awarded for this project, and all future years have been removed. University of California Berkeley may request funds to support patient safety and orderly closeout of the project, and remaining funds will be deobligated. Funds used to support

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:05 AM

any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award adjusts the end dates to 4/30/2025.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 6/27/2024 ALSO APPLY TO THIS AWARD:

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 in a revised Notice of Award. The certification should be sent via email to pg38h@nih.gov and shacklefords@mail.nih.gov.

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.

REQUIREMENT: This award is subject to the conditions set forth in PAR-21-271, Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 Independent Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 08/17/2021, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PAR-21-271.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:05 AM

REQUIREMENT: A complete application for the Independent Investigator Phase (R00) must be submitted to the NIMHD no later than 2 months prior to the K99 award's project period end date. As indicated in the Program Announcement for this mechanism, the applicant must demonstrate in the application that an independent tenure-track, full-time assistant professor position has been secured. Applicants are strongly encouraged to review the Program Announcement and discuss with the Program Official listed below, as early as possible, proposed transition plans.

Award of the R00 phase is not automatic. Applicants that are approved to transition will receive a Notice of Grant Award reflecting the new grant mechanism, the dollar amount, and the new recipient organization (if applicable). Applicants that are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This letter typically will be sent within 60 days of receipt of the R00 application.

Since the principal purpose of this award is to transition the principal investigator to an independent investigator, no request to change the principal investigator will be considered.

A Federal Financial Report (SF 425) must be submitted within 120 days of the end date of the K99 phase.

In addition, if the R00 phase is NOT funded, grant closeout documents consisting of a Final Invention Statement (HHS 568), and a final RPPR must also be submitted within 120 days of the expiration date. Closeout documents should be submitted through the NIH Commons available at https://commons.era.nih.gov/commons/. Additional information is available at the Commons Homepage or by contacting the eRA Helpdesk at: commons@od.nih.gov or (866) 504-9552.

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

SPREADSHEET SUMMARY
AWARD NUMBER: 5K99MD018629-02 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA BERKELEY

Budget	Year 2
Salaries and Wages	$90,000
Fringe Benefits	$12,600
Personnel Costs (Subtotal)	$102,600
Travel	$7,473
Other	$15,800
TOTAL FEDERAL DC	$125,873
TOTAL FEDERAL F&A	$10,070
TOTAL COST	$135,943

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	8%
F&A Cost Base 1	$125,873
F&A Costs 1	$10,070

Version: 25 - 2/15/2024 9:51 AM | Generated on: 4/30/2025 12:05 AM

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Young, Margaret (NIH/NICHD) [E]
Subject: FW: Grant Termination Notification
Date: Friday, March 21, 2025 1:21:40 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 12:35 PM
To: kblanchard@ibisreproductivehealth.org
Subject: Grant Termination Notification

3/21/2025

Kelly Blanchard
Ibis Reproductive Health
kblanchard@ibisreproductivehealth.org

Dear Kelly Blanchard:

Effective with the date of this letter, funding for Project Number 5R01HD109320-02 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 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow

the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD109320
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
2067 MASSACHUSETTS AVE
STE 26
CAMBRIDGE, MA 02140

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFRBQTK9H5M3

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD

hmoseson@bisreproductivehealth.org
503-550-8076

8. Authorized Official
Kelly Blanchard
kblanchard@bisreproductivehealth.org
617-349-0027

Federal Agency Information

9. Awarding Agency Contact Information
Yvonne C. Talley
Grants Management Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
talleyy@mail.nih.gov
301-496-7432

10. Program Official Contact Information
Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ronna.popkin@nih.gov
301-827-5121

Federal Award Information

11. Award Number
5R01HD109320-02

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

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 06/01/2024 – **End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20a. Direct Cost Amount	$0
20b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$477,618
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$477,618
26. Project Period Start Date 09/21/2023 – **End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,047,555

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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

A2532

NIH_GRANTS_004790

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R01HD109320-02 REVISED

Principal Investigator(s):
Heidi Serene Mabeson Lidow PHD

Award e-mailed to: kblanchard@bisreproductivehealth.org

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 BIS REPRODUCTIVE HEALTH 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 R01HD109320. 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/policy.htm for the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$110,268

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

Fringe Benefits	$30,875
Personnel Costs (Subtotal)	$141,143
Consultant Services	$4,275
Other	$3,717
Subawards/Consortium/Contractual Costs	$266,213
Equipment or Facility Rental/User Fees	$22,583
Federal Direct Costs	$437,931
Federal F&A Costs	$39,687
Approved Budget	$477,618
Total Amount of Federal Funds Authorized (Federal Share)	$477,618
TOTAL FEDERAL AWARD AMOUNT	$477,618
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (2) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01HD109320-02	$477,618
3R01HD109320-02S1	$59,000
TOTAL	**$536,618**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$477,618	$536,618

Fiscal Information:

Payment System Identifier:	1030382773A1
Document Number:	RHD109320A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
HD	8014702	$427,618
OD	8055729	$50,000

NIH Administrative Data:
PCC: PDB-RP/**OC**: 41025/**Released**: 03/25/2025
Award Processed: 03/26/2025 12:15:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD109320-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01HD109320-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/26/2025 12:15 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 Research, 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 full NIH award terms implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. 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 Reporting at https://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/. 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, UF2, 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_instructionguide.pdf. Any guidance specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that RPPR 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 PPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) 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 https://www.hhs.gov/ocr/civilrights/understanding/disability/index.html
- HHS funded health and education programs must be administered in an environment free of sexual harassment; 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 expects of institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R01HD109320-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, it is the policy of NIH not to prioritize such research programs.

CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
  - Options pertaining to receiving further intervention, continuing follow-up, if required
  - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
  - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
  - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

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

NIH is taking this enforcement action in accordance with 2 CFR § 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.

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Funding Level
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Co-fund
Co-funding support in the amount of $50,000 from the Office of Behavioral and Social Sciences Research (OBSSR).

Clinical Trial Terms

Dissemination Policy
The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **07/05/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of their knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

Clinical Trial Study/Studies:
STUDY NUMBER: 427630

Risk Assessment

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

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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".

Consortium

This award includes funds awarded for consortium activity with the following:
Mount Holyoke College
Stanford University

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01HD109320-02REVISED

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 2
Salaries and Wages	$110,268
Fringe Benefits	$30,875
Personnel Costs (Subtotal)	$141,143
Consultant Services	$4,275
Other	$3,717
Subawards/Consortium/Contractual Costs	$266,213
Equipment or Facility Rental/User Fees	$22,583
TOTAL FEDERAL DC	$437,931
TOTAL FEDERAL F&A	$39,687
TOTAL COST	$477,618

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	20.2%
F&A Cost Base 1	$196,468
F&A Cost s1	$39,687

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

From: Grant, Priscilla (NIH/NIMHD) [E]
To: Phillips, Michelle (NIH/NIMHD) [E]
Subject: FW: Grant Termination Notification
Date: Sunday, March 23, 2025 7:58:36 PM
Attachments: image001.jpg
image002.png

Please upload, Michelle. Thanks

Priscilla Grant, JD
Chief Grants Management Officer, NIMHD

National Institutes of Health
Department of Health and Human Services
Phone: 301-594-8412

From: Grant, Priscilla (NIH/NIMHD) [E]
Sent: Saturday, March 22, 2025 12:59 AM
To: Cotton, Paul (NIH/NIMHD) [E] <paul.cotton@nih.gov>
Cc: Do, Jimmy (NIH/NIMHD) [E] <Jimmy.Do@nih.gov>; Sonnenberg, Kenneth (NIH/NIMHD) [E] <kenneth.sonnenberg@nih.gov>; Johnson, Lemel (NIH/NIMHD) [E] <lemel.johnson@nih.gov>
Subject: FW: Grant Termination Notification

Terminated

From: Ta, Kristin (NIH/OD) [E] <kristin.ta@nih.gov> **On Behalf Of** Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 1:43 PM
To: Grant, Priscilla (NIH/NIMHD) [E] <grantp@mail.nih.gov>
Subject: FW: Grant Termination Notification

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Friday, March 21, 2025 12:30 PM
To: research_admin@harvardpilgrim.org
Subject: Grant Termination Notification

3/21/2025

Cary Williams
Harvard Pilgrim Health Care, Inc.
research_admin@harvardpilgrim.org

Dear Cary Williams:

Effective with the date of this letter, funding for Project Number 5R01MD015256-05 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 3/1/2024, 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 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)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# R01MD015256
Federal Award Date
03/23/2025

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Brittany Michelle Charlton, DSC
Assistant Professor
bcharlton@mail.harvard.edu
617-466-9262

8. Authorized Official
Charlotte Johnson
research_admin@harvardpilgrim.org

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
Priscah Mujuru
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
priscah.mujuru@nih.gov
301-594-9765

Federal Award Information

11. Award Number
5R01MD015256-05

12. Unique Federal Award Identification Number (FAIN)
R01MD015256

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Sexual orientation-related disparities in obstetrical and perinatal health

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 **– 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	$802,428
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$802,428
26. Project Period Start Date 05/16/2021 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,917,674

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: 3/25/2025 12:07 AM

A2543

NIH_GRANTS_004810

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5R01MD015256-05 REVISED

Principal Investigator(s):
Brittany Michelle Charlton, DSC

Award e-mailed to: research_admin@hphci.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. 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: 3/25/2025 12:07 AM

Salaries and Wages	$246,010
Fringe Benefits	$68,883
Personnel Costs (Subtotal)	$314,893
Travel	$6,729
Subawards/Consortium/Contractual Costs	$260,235
Publication Costs	$5,000
Federal Direct Costs	$586,857
Federal F&A Costs	$215,571
Approved Budget	$802,428
Total Amount of Federal Funds Authorized (Federal Share)	$802,428
TOTAL FEDERAL AWARD AMOUNT	$802,428
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$802,428	$802,428

Fiscal Information:
Payment System Identifier: 1042452600A1
Document Number: RMD015256B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MD	8472687	$802,428

NIH Administrative Data:
PCC: CPS01PM / **OC**: 41025 / **Released**: 03/23/2025
Award Processed: 03/25/2025 12:07:27 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MD015256-05 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 – 5R01MD015256-05 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: 3/25/2025 12:07 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).

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) R01MD015256. 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 – MD SPECIFIC AWARD CONDITIONS – 5R01MD015256-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

INFORMATION: 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 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. Harvard Pilgrim Health Care, Inc may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. 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: 3/25/2025 12:07 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.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 2/19/2025 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award's end date has been adjusted to 4/30/25 due to the large unobligated balance.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 05/30/2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award has been issued in accordance with NIMHD's Fiscal Year 2024 funding policy for non-competing awards.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 02/03/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/20, 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:
http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: The recipient is required to follow the data sharing plan included in the application and may not implement any changes in the plan without the written prior approval of the NIMHD.

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.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

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

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD015256-05 REVISED

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 5
Salaries and Wages	$246,010
Fringe Benefits	$68,883
Personnel Costs (Subtotal)	$314,893
Travel	$6,729
Subawards/Consortium/Contractual Costs	$260,235
Publication Costs	$5,000
TOTAL FEDERAL DC	$586,857
TOTAL FEDERAL F&A	$215,571
TOTAL COST	$802,428

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	66%
F&A Cost Base 1	$326,622
F&A Costs 1	$215,571

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

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# R01MD016384
Federal Award Date
03/20/2025

Recipient Information

1. Recipient Name
BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA
2200 VINE ST # 830861
LINCOLN, NE 68503

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1470049123A8

4. Employer Identification Number (EIN)
470049123

5. Data Universal Numbering System (DUNS)
555456995

6. Recipient's Unique Entity Identifier
HTQ6K6NJFHA6

7. Project Director or Principal Investigator
Katie M Edwards, PHD
Associate Professor
katie.edwards@unl.edu
6034223207

8. Authorized Official
Craig Goodrich

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
ARIELLE SAMANTHA Gillman
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
arielle.gillman@nih.gov
301-402-1366

Federal Award Information

11. Award Number
5R01MD016384-03

12. Unique Federal Award Identification Number (FAIN)
R01MD016384

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2024 **– End Date** 12/31/2024	
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	$767,135
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$767,135
26. Project Period Start Date 07/22/2022 **– End Date** 12/31/2024	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,340,662

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: 3/21/2025 12:06 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5R01MD016384-03 REVISED

Principal Investigator(s):
Katie M Edwards, PHD

Award e-mailed to: unlospawards@unl.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEBRASKA LINCOLN 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 R01MD016384. 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: 3/21/2025 12:06 AM

Salaries and Wages	$115,053
Fringe Benefits	$42,107
Personnel Costs (Subtotal)	$157,160
Consultant Services	$3,125
Materials & Supplies	$1,000
Travel	$1,585
Other	$281,336
Subawards/Consortium/Contractual Costs	$76,395
Federal Direct Costs	$520,601
Federal F&A Costs	$246,534
Approved Budget	$767,135
Total Amount of Federal Funds Authorized (Federal Share)	$767,135
TOTAL FEDERAL AWARD AMOUNT	$767,135
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$767,135	$767,135

Fiscal Information:
Payment System Identifier: 1470049123A8
Document Number: RMD016384A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MD	8472687	$767,135

NIH Administrative Data:
PCC: IBB03AG / **OC**: 41025 / **Released**: 03/20/2025
Award Processed: 03/21/2025 12:06:15 AM

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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.
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some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This 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.

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Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

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- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 5R01MD016384-03 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.

INFORMATION: It is the policy of NIH not to prioritize research activities that focus on gender identity. 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. Therefore, this project is terminated. The University of Nebraska Lincoln may request funds to support patient safety and orderly closeout of the project. Funds used to

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/21/2025 12:06 AM

support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ISSUED ON 03/13/2025 ALSO APPLY TO THIS AWARD:

INFORMATION: In accordance with the relinquishing statement dated December 11th, 2024, this revised award terminates support for this project on December 31st, 2024.

It is the policy of NIH not to prioritize research activities that focus on gender identity. This project no longer effectuates agency priorities. Therefore, this project is terminated. The University of Nebraska Lincoln 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., Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ISSUED ON 06/21/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/2020, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address: https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

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.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD016384-03 REVISED

INSTITUTION: UNIVERSITY OF NEBRASKA LINCOLN

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/21/2025 12:06 AM

Budget	Year 3
Salaries and Wages	$115,053
Fringe Benefits	$42,107
Personnel Costs (Subtotal)	$157,160
Consultant Services	$3,125
Materials & Supplies	$1,000
Travel	$1,585
Other	$281,336
Subawards/Consortium/Contractual Costs	$76,395
TOTAL FEDERAL DC	$520,601
TOTAL FEDERAL F&A	$246,534
TOTAL COST	$767,135

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$444,206
F&A Costs 1	$246,534

Version: 25 - 2/15/2024 9:51 AM | Generated on: 3/21/2025 12:06 AM

From: Ta, Kristin (NIH/OD) [E] on behalf of Bulls, Michelle G. (NIH/OD) [E]
To: Linde, Emily (NIH/NIAID) [E]
Subject: FW: Grant Termination Notification
Date: Monday, March 24, 2025 8:34:03 PM
Attachments: image002.png

From: Bulls, Michelle G. (NIH/OD) [E]
Sent: Monday, March 24, 2025 3:52 PM
To: david.candelmo@hmhn.org
Subject: Grant Termination Notification

3/24/2025

Candelmo, David
Hackensack University Medical Center
david.candelmo@hmhn.org

Dear Candelmo, David:

Effective with the date of this letter, funding for Project Number 1U19AI171401-01 is hereby terminated pursuant to the Fiscal Year 2022 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 2022 Policy Statement applies to your project because NIH approved your grant on 5/16/2022, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2022 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, 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)

Center for Discovery & Innovation
Member of Hackensack Meridian *Health*

The Rockefeller University 1901
SCIENCE FOR THE BENEFIT OF HUMANITY

April 03, 2025

Dr. Matt Memoli
National Institutes of Health
Office of the Director, Division of Allergy, Immunology, and Infectious Diseases
Bethesda, MD

Re: Appeal for Reconsideration of Termination of Funding for MAVDA (Project Number 1U19AI171401-01)

Dear Dr. Memoli,

We are writing to formally request a reversal of the decision to terminate funding for the Metropolitan Antiviral Drug Accelerator (MAVDA), Project Number 1U19AI171401-01, as outlined in the termination notice received on March 24, 2025 (attached). The stated reason for the termination appears to be based on a misunderstanding. According to the Revised Award notice:

> *"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."*

However, neither the MAVDA grant nor the broader Antiviral Drug Accelerator (AViDD) Centers for Pathogens of Pandemic Concern (RFA-AI-21-050) program under which the grant was solicited were intended solely to address the COVID-19 pandemic. Rather, **MAVDA was established to enhance national health security by strengthening preparedness and readiness against emerging and unforeseen viral threats far beyond SARS-CoV-2**. The program specifically supports the development of countermeasures against viruses such as MERS, other human coronaviruses, Dengue, Yellow Fever, Chikungunya, and La Crosse. These viruses, which cause acute illness, may also trigger debilitating long-term chronic immunologic conditions. Hence, early intervention is critical.

The MAVDA consortium was designed as a public-private partnership leveraging expertise, resources, and combined investments from the NIH and industry leaders like Merck to create a unique drug accelerator. In just three years, MAVDA members have made exceptional progress in advancing therapeutic countermeasures for these global health challenges, with one drug candidate already in early-stage clinical development and several others in advanced preclinical stages.

MAVDA has emerged as a quintessential new national model to rapidly develop therapeutic countermeasures against a broad spectrum of infectious disease threats, spanning viruses, bacteria, fungi, and parasites. We believe that the premature termination of funding may be an unintended consequence of MAVDA's initial focus on SARS-CoV-2. However, the current mature program aligns closely with national biodefense priorities and biothreat risk mitigation strategies, which are unrelated to COVID-19. Given the extensive scientific, economic, and national security impact of the work conducted under this grant, we respectfully urge reconsideration of the decision to terminate the award.

We submit the following key points for consideration:

Scientific Merits

- MAVDA has made significant progress in advancing drug candidates through critical stages of development. We have moved one drug candidate into clinical trials (Aligos) and have three others in preclinical development, all targeting high-priority viruses.
- Key achievements include -
    - **11 Research Publications**
    - **14 Patents**
    - **>3 near IND-enabling programs**
    - Programs supporting the development of **novel viral mechanisms** (NSP14, NiRAN).
    - Development of **new assays and research tools**.
- The program has demonstrated its capacity to rapidly respond to emerging infectious diseases, creating valuable assets that could be pivotal for future outbreaks, including potentially life-threatening diseases such as MERS.
- The therapeutic candidates under development may also have utility for addressing Long COVID, further extending the relevance and impact of the MAVDA program beyond its original pandemic focus.

Economic Benefits and Return on Investment

- Extensive public funds have been invested in MAVDA thus far, and the premature termination of the program would waste these investments, both in terms of scientific progress, national security, and economic potential.
- Public funds were leveraged with substantial commercial investment from industry partners such as Merck (Merck Sharp and Dohme Corp) and Aligos Therapeutics Inc., making this program a **model of cost-effective drug discovery** with the potential for significant return on investment as products move toward commercialization.
- Cutting MAVDA now would dismantle years of progress, resulting in a significant loss of potential economic and public health benefits.

Pandemic Preparedness Infrastructure

- The MAVDA program has created a **critical infrastructure** to develop and test therapeutics for infectious diseases, including those that represent immediate and ongoing threats to the United States, such as influenza, H5N1, and other emerging viral diseases.
- This infrastructure, which includes collaboration with academic institutions and industry leaders across the United States, provides the country with the necessary tools and expertise to respond rapidly to future pandemics or bioweapon threats.
- By dismantling this infrastructure now, we risk losing valuable capabilities that would take years to rebuild, potentially leaving the U.S. unprepared for future outbreaks of deadly diseases.

National Security and Public Health Readiness

- The work conducted through MAVDA addresses **critical national security and public health needs**, with the goal of developing broad-spectrum antiviral drugs to combat both naturally occurring pandemics and bioweapons.
- The scale of the program, with multiple centers across the U.S., represents a nationwide effort that brings together the best minds in drug discovery, with tangible benefits for public health and national security.

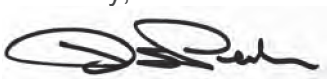
NIH Guidance on No-Cost-Extension Request and Approvals

- At the conclusion of the second year of this project, NIH officials advised our AviDD center that a No-Cost Extension (NCE) could be requested for Year 4 to optimize the use of remaining funds and ensure that our most promising drug candidates reach critical development milestones.
- This guidance has informed our planning. As a result, we have strategically allocated funds for IND-enabling studies in Year 4, which are essential for advancing the projects and maintaining continuous funding for the associated personnel.

Given the points outlined above, we respectfully request that the NIH reconsider its decision to terminate funding for MAVDA. With continued support, MAVDA can successfully achieve its goals by advancing therapeutics that protect the health of Americans and contribute to broader efforts to combat infectious diseases. If needed, **we are prepared to restate our sole effort for development of therapeutic countermeasures against non-coronavirus-related threats that fully align with NIH's current priorities.** We are eager to collaborate with you to find a solution that preserves the progress we have made and ensures that the public funds already invested yield the greatest possible benefit.

Thank you for your attention to this urgent matter. I look forward to your response and to the possibility of further discussion.

Sincerely,



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