Exhibit F

UW-AOR on behalf of Tracking Grants.gov AOR emails via UW-AOR
uw-aor@u.washington.edu
[UW-AOR] Grant Termination Notification
Friday, March 21, 2025 9:38:52 AM
image001.jpg
image002.png
ATT00001.txt



3/21/2025

Rhodes, Carol
University Of Washington
uw-aor u.washington.edu

Dear Rhodes, Carol:

Effective with the date of this letter, funding for Project Number 1R21AI183907-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/10/2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to d

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9]

See 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Exhibit G



March 20, 2025

Carol Rhodes
University of Washington
uw-aor u.washington.edu

Dear Carol Rhodes:

Effective with the date of this letter, funding for Project Number 1R01 TW012904-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health (NIH) Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 9, 2024, and obligations generally should be determined by reference to the law in effect when the grants were made. [3]

The 2024 Policy Statement includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4] According to the Policy Statement, NIH may terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination [b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities.

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (DEI) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision, [6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget s regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 17:04:13 -04'00'

Michelle G. Bulls, on behalf of Bruce Butrum, Chief Grants Management Officer, Fogarty International Center
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 28

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

SUPPLEMENTAL DECLARATION OF MARI OSTENDORF

I, Mari Ostendorf, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice Provost of Research of University of Washington. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Supplemental Declaration in support of the States' Motion for Temporary Restraining Order.

3. On April 1, I signed a declaration in which I testified about nine separate NIH grant terminations received by UW researchers.

4. On April 2, in a single day, UW researchers received at least three more NIH grant terminations.

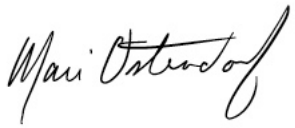
5. In one case, NIH terminated a K99 grant (awarded to postdoctoral scientists pursuing research careers) under the Maximizing Opportunity for Scientific and Academic Independent Careers program. In another, NIH terminated a grant under the Research Education Program, a program designed to support programs that enhance diversity in the scientific research

field. And in the third, NIH terminated an F31 grant under the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research.

6. In each case, the only explanation NIH gave for these terminations is that they were "due to changes in NIH/HHS priorities." The termination notices are attached hereto as **Exhibits H-J**.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Executed this 2nd day of April 2025, in Seattle, Washington.



MARI OSTENDORF
Vice Provost of Research
University of Washington

Exhibit H

[redacted]

[EXTERNAL]

From: UW-AOR <uw-aor-bounces@mailman13.u.washington.edu> **On Behalf Of** Tracking Grants.gov AOR emails via UW-AOR
Sent: Wednesday, April 2, 2025 10:51 AM
To: uw-aor@u.washington.edu
Subject: [UW-AOR] NIGMS Funding Update

Re: K99GM141364-02

Dear Rhodes, Carol,

As Business Official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Maximizing Opportunity for Scientific and Academic Independent Careers (MOSAIC)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

Exhibit I

From: Office Of Sponsored Programs
To: Carol Rhodes; Amanda C Snyder
Cc: Adelia Yee
Subject: FW: NIGMS Funding Update
Date: Wednesday, April 2, 2025 11:09:11 AM

Hi,

Here is the 3rd one.

Dianna

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 11:01 AM
To: Office Of Sponsored Programs <osp@uw.edu>
Subject: NIGMS Funding Update

Re: F31GM155953-01

Dear Carol Rhodes,

As Business Official for the above referenced award (PI FERNANDO BANALES MEJIA), I am writing to let you know that due to changes in NIH/HHS priorities, the **Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include the grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

Exhibit J

From: Office Of Sponsored Programs
To: Carol Rhodes; Amanda C Snyder
Cc: Adelia Yee
Subject: FW: NIGMS Funding Update
Date: Wednesday, April 2, 2025 10:32:24 AM

Good Morning,

Please see the notice below.

Dianna

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 10:15 AM
To: Office Of Sponsored Programs <osp@uw.edu>
Subject: NIGMS Funding Update

Re: GM086304-14

Dear Rhodes, Carol,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Postbaccalaureate Research Education Program (PREP)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 29

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF DOROTA A. GREJNER-BRZEZINSKA

I, Dorota Grejner-Brzezinska, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice Chancellor for Research at the University of Wisconsin-Madison ("UW-Madison"). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UW-Madison staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Vice Chancellor for Research at the University of Wisconsin-Madison, a position I have held since 2024. In this role, I have responsibility for overseeing the university's research enterprise with more than $1.7 billion in annual research expenditures. My office also includes administration of 20 cross-campus research and service centers. The mission of the Office of the Vice Chancellor for Research is to advance excellence in research and scholarship,

to support our multidisciplinary research centers and institutes, and to provide campus-wide administrative infrastructure to support and advance the research enterprise. Prior to holding this position, I was the Vice President of the Office of Knowledge Enterprise, Associate Dean for Research in the College of Engineering, and a Professor of Civil, Environmental and Geodetic Engineering at The Ohio State University. At Ohio State, I also served as senior vice president for corporate and government partnerships, focusing on growing research talent and helping launch new research institutes and centers. I have mentored 16 doctoral students and secured nearly $39 million in research funding for my own research, which is centered on GPS, the Global Positioning System. My laboratory developed the first fully digital and directly geo-referenced Airborne Integrated Mapping System, combining high-resolution digital, aerial camera images with GPS and inertial technology. I have served on the President's Council of Advisors on Science and Technology, and was appointed to the National Science Board in 2023. I am also a fellow of the American Association for the Advancement of Science, the Institute of Navigation, and the Royal Institute of Navigation and member of the National Academy of Engineering. Additionally, I serve as principal investigator of the National Science Foundation's Engineering Research Visioning Alliance.

4. UW-Madison is the flagship university of the University of Wisconsin System. The University of Wisconsin System's statutory mission, as set forth in Wis. Stat. § 36.01(2), is:

> to develop human resources, to discover and disseminate knowledge, to extend knowledge and its application beyond the boundaries of its campuses and to serve and stimulate society by developing in students heightened intellectual, cultural and humane sensitivities, scientific, professional and technological expertise and a sense of purpose. Inherent in this broad mission are methods of instruction, research, extended training and public service designed to educate people and improve the human condition. Basic to every purpose of the system is the search for truth.

5. UW-Madison is composed of 13 schools and colleges and, as of the Fall of 2024, enrolls over 52,000 students and employs over 27,000 faculty and staff.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections and advisory council meetings. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation in which grant proposals that had previously been reviewed positively have remained unfunded indefinitely. These are grant applications that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given an overall impact score and, generally, a percentile rank (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. Percentile ranks are based on an application's overall impact score in comparison with other applications reviewed by the same study section in a series of past meetings. Grant paylines are set by particular NIH Institutes/Centers (IC).

7. The NIH meeting blockade severely impacts the UW-Madison by delaying or potentially removing support for critical research into diseases and disorders that affect human health and quality of life. Laboratories engaged in this vital research will be disrupted by these delays, hindering scientific progress. If research is halted, it will be extremely difficult to restart due to the absence of dedicated and knowledgeable scientists and well-tooled scientific facilities. Diminished NIH support for research is also likely to reduce the future scientific workforce if trainee positions go unfunded and consequently unfilled. As such, delay or reduction of NIH funding will not only affect science in the present day, but compromise scientific progress in future generations.

8. Approximately one third of sponsored research at UW-Madison is awarded by the NIH. For this reason, even weeks of delays in funding result in considerable budgetary reductions, and the impact is expected to compound rapidly. Our institution has begun implementing strategic cost reductions, and as these grow the advancement of science will surely be negatively impacted.

Reliance on NIH Funding

9. In fiscal year 2024, UW-Madison received direct funding from the National Institutes of Health ("NIH") to support 588 projects, totaling $404,722,816.95.

10. UW-Madison receives NIH grants across a variety of institutes encompassed within the NIH, including Eunice Kennedy Shriver National Institute of Child Health and Human Development, John E. Fogarty International Center, National Cancer Institute, National Center for Advancing Translational Sciences, National Center for Complementary and Integrative Health, National Eye Institute, National Heart, Lung, and Blood Institute, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Biomedical Imaging and Bioengineering, National Institute of Child Health and Human Development, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute on Deafness and Other Communication Disorders, National Institute on Drug Abuse, National Institute on

Minority Health and Health Disparities, National Library of Medicine, and the Office of Data Science Strategy.

11. Through those direct NIH grants, UW-Madison funds 4,942 researchers and staff.

12. The work done by UW-Madison on NIH-funded projects provides scientific education and research training in all areas of medical and health sciences, biology, public health, biochemistry, psychology, and other disciplines.

13. UW-Madison provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Wisconsin economy. For instance, more than 35,000 engineering, medicine, nursing and pharmacy graduates live in the state.

Typical Timeline and Processes for NIH Grant Awards

14. The Office of Research and Sponsored Programs at UW-Madison works with researchers to submit grant applications and tracks grant applications and awards.

15. I have an understanding of the NIH grant process based on my current work as Vice Chancellor for Research at UW-Madison and previous work as Vice President of the Office of Knowledge Enterprise and Associate Dean for Research in the College of Engineering at Ohio State University. My experience in those roles spans 7.5 years combined.

16. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given an overall impact score that reflects this scientific merit. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors as every institute or center, sometimes referred to as an "IC," is different. Some ICs publish paylines, meaning the percentiles of grants they will fund, and some do not. Published paylines generally range from 8-20%. Most of the standing study section reviews result in an overall impact score and percentile for each proposal, but many others will only result in an overall impact score and not a percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives.

18. After the study section meeting, grant applications and corresponding overall impact scores and/or percentile ranks are sent to an IC's "advisory council" for the second stage of NIH review, where the ultimate decision on whether to fund the grant is made. After the advisory council meets, a Notice of Award is issued if the grant will be funded.

19. The process for competitive renewals of NIH grants is very similar.

20. The budget process at UW-Madison relies upon the NIH grant application, review, and approval cycle. Historically, we have used a range of 4-6 months from submission for the review and scoring process to be complete. This general timeline supports sound planning for continuity of funding at the project level, which in turn flows upwards to institution-wide budgetary planning.

21. Once a grant receives a Notice of Award, UW-Madison is able to ascertain whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

22. Since late January 2025, UW-Madison has seen an unusual number of delays in the processing of NIH grant applications. Study sections and advisory councils have been

delayed, canceled, or otherwise not scheduled, and grant application scoring has been significantly delayed, creating a great deal of inefficiency in this process.

23. UW-Madison has not received formal notice of changes for many of these grants. For others, UW-Madison has received only a notification that proposals are paused or under review.

24. As of March 31, 2025, the University of Wisconsin-Madison has 829 direct proposals and 423 subaward proposals pending NIH review. These proposals, submitted since January 2024, request a total of $1,876,612,449 in direct NIH funding and $249,508,887 in incoming NIH subaward funding.

Terminations of NIH Grants

25. I am aware of four NIH grants to UW-Madison having been terminated since March 21, 2025. The total amount of funding anticipated under these awards was $25,149,959. Of that amount, $12,631,870 has not been disbursed to UW-Madison.

26. The terminations that I am aware of UW-Madison having received as of March 31, 2025 are attached hereto as Exhibits A - D.

27. These terminations will result in the loss of an anticipated $12,631,870 in research funding to UW-Madison.

28. The termination documentation for these grants has included statements regarding the lack of necessity for the research or unsubstantiated statements indicating a lack of scientific merit and other value. In most cases, the termination documentation noted that the research no longer "effectuates agency priorities."

29. Those termination notices that referenced the potential for corrective actions stated that there is no corrective action that can be taken to ensure the grant aligns with agency

priorities. However, prior to receipt of the termination, UW-Madison had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was UW-Madison provided with any updated "agency priorities" with which its research must align.

30. NIH Project 5R01AI158463 (Infectious Disease Research Grant), an R01 grant awarded to UW–Madison's Kirchdoerfer lab, focuses on investigating the molecular mechanisms of SARS-CoV-2 replication, specifically examining the functions of the virus's polymerase complex. The project aims to provide foundational insights into how multiple protein subunits contribute to coronavirus genetic replication, essential knowledge for developing effective antiviral therapeutics. Significant outcomes achieved include rapid publication of research findings, open sharing of structural data, and identification of critical viral components—such as the SARS-CoV-2 nsp14 exonuclease—that play roles in viral replication and antiviral drug resistance. Benchmarks reported through regular Research Performance Progress Reports (RPPRs) include timely publication of findings and sharing of structural data, compliance with NIH requirements, and substantial investment in core microscopy facilities explicitly supporting this research. The unexpected termination disrupts ongoing experiments on drug resistance mechanisms and halts crucial research activities, adversely affecting laboratory personnel and undermining public health preparedness against future coronavirus threats.

31. NIH Project 1P01AI165077-01 (PanCorVac – Center for Pan-Coronavirus Vaccine Development), a Program Project (P01) grant, established the PanCorVac Center at UW–Madison, aiming to develop protein-based vaccines effective against multiple coronavirus variants and future pandemic threats. The research has demonstrated significant scientific progress, including successful development and early animal testing of promising vaccine

candidates, resulting in peer-reviewed publications validating robust immune responses. The Center has collaborated with multiple subrecipient institutions and conducted comprehensive preclinical studies designed to move candidate vaccines toward human clinical trials. Reported benchmarks include completed testing of vaccine candidates in animal models, seven peer-reviewed publications, and substantial data generation to support translational research efforts to benefit people.

32. NIH Project 5R01MD018751 (Minority Health and Health Disparities Research Grant), an R01 grant awarded to Dr. Elliot Tebbe in UW-Madison's School of Nursing and Dr. Stephanie Budge in the School of Education, aims to identify essential components of social support that address known mental health disparities (e.g., anxiety, depression, suicidality) among transgender and nonbinary people, to develop and validate a new measure of social support for this population for use in future research and clinical settings, and to determine the protective effects of social support on mental health over time. Significant achievements in the progress of this grant prior to termination (from August 2024 to March 2025) included hiring all members of the research team (14 personnel in total) and beginning work on the development of an innovative data collection tool to capture intensive data on daily social experiences as part of project set up. The researchers were also nearing completion of a systematic review of the scientific literature on social support, and had completed qualitative interviews with national community leaders on community social support structures and strategies. This grant was terminated at the start of Year 2, with an anticipated four years remaining on the award. Despite the significant process made in a shortened Year 1 timeframe as reported in the Research Performance Progress Report (RPPR), the termination of this grant will eliminate the support already committed to graduate students, research staff, and infrastructure critical to the research.

33. NIH Project P01HD109850 (Child Health and Human Development Extramural Research), a P01 grant, was awarded to Dr. Megan Moreno and Dr. Ellen Selkie in the Department of Pediatrics, and Dr. Christopher Cascio in the School of Journalism and Mass Communication. The grant involves three independent projects and two university research cores. This grant's three projects all address a major health issue in America: the impact of media on adolescent physical and mental health, health behaviors, and brain development. This research program is the largest endeavor of its kind, with a goal of recruiting four hundred youth from across Wisconsin; the researchers had already recruited more than three hundred. Thus far, team members have presented preliminary findings from their ongoing longitudinal study, including 17 abstracts accepted across seven different local, national, and international conferences. The researchers have published one paper and a second is under review. Additionally, the project has helped uncover preliminary findings showing that self-generated content on social media is associated with increased ventromedial prefrontal cortex (VMPFC) activity compared to other-generated content (e.g., peer generated). This brain activity is associated with increased health (i.e., physical activity) and decreased risk (i.e. alcohol use) behaviors. The finding suggests that sharing personal information on social media integrates into adolescents' attitudes and actions and supports one mechanism that may underlie how self-posts influence behavior. Additionally, through a variety of approaches, including cyberethnography and criterion-based coding, the researchers have begun providing a rich picture of adolescent life online, particularly among middle schoolers, and its health and well-being correlates.

Comparisons Across Administrations

34. UW–Madison has never experienced this volume of unexplained delays or procedural breakdowns, including under both Democratic and Republican administrations.

35. Noncompetitive renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

36. The current approach is, in our experience, without precedent.

Impact on Institutional Operations

37. The uncertainty stemming from delays and cancellation of study sections makes both near- and long-term budgetary planning especially difficult. The workforce in support of research must align with available funding. Due to unpredictability regarding the extent, timeline and nature of diminished support, UW-Madison lacks the information necessary to make timely decisions necessitated by the change in NIH funding practices. UW-Madison anticipates losing well-trained employees from the research enterprise in the coming months; without clarity around future research support needs, rebuilding these human resources in the future will be costly and challenging. The productivity of researchers has already been discernibly impacted by discontinuity in funding and the time and effort required for managing communications and planning in this highly ambiguous period. While this is not quantifiable at this time, this lost work is a real cost. Similarly, facilities costs and operational support of research, including administrative and compliance support, will not be able to continue to be supported at the same level as grant funding is delayed or reduced. The institution is evaluating various scenarios, attempting to evaluate financial risk, with very little visibility into the approaching NIH funding landscape. As the duration of this period of ambiguity extends, prudent financial management will necessitate actions that will have a long tail; these are likely to harm the institution's fiscal health and make a return to efficient and excellent support of research difficult.

38. Several shared research cores have seen significantly decreased usage due to grant uncertainty. Research cores provide vital services available to multiple researchers and require continued financial support through grant-funded user fees to serve their critical functions.

Admissions, Training and Workforce Disruptions

39. UW-Madison uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the doctoral student level.

40. Of those programs that have reported admissions offers for Fall 2025 thus far, the number of admissions offers for doctoral students has decreased by approximately 25% due to uncertainty over grant funding because of the delays in reviewing and awarding NIH grants and because of NIH funding halts.

41. Multiple programs that have extended admissions offers have needed to clarify to admitted students that continuous funding support throughout the course of their doctoral program cannot be guaranteed. Prior to this spring, 92% of doctoral programs at UW-Madison have been able to offer guaranteed funding for 4-5 years. This is an important mechanism for UW-Madison to be competitive for the most talented doctoral students who will perform cutting edge research that advances disease diagnosis and treatment, and who become the future STEM workforce of the U.S.

42. I am aware of two NIH T32 training grants that have received fundable scores and have been affected by review and award delays as of March 31, 2025. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas. If T32 grants are not awarded in a timely manner, trainees who would receive funding under them will not have access to funding support for training intended to prepare them for

careers that meet the health-related research needs of the U.S. UW-Madison does not have a readily available alternative source of funding to support such trainees.

43. This instability is affecting the recruitment of quality research trainees. The inability to recruit quality research trainees will have continuing effects on the research capabilities of UW-Madison, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

44. UW-Madison is increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

Irreparable Harm

45. The delays have disrupted ongoing research due to the uncertainties in the timing of study section and advisory council reviews, and created setbacks for research at UW-Madison going forward. Some researchers have been unable to commit to bringing on graduate students or maintaining current trainees due to funding uncertainty, and have been forced to consider abandoning studies that historically would have been expected to receive funding.

46. In many cases, there is no way to recover the lost time, research continuity, or training value once research is disrupted.

47. The grants that have been terminated have the potential to achieve results that would have advanced public health, depriving Americans of the benefits derived from biomedical research. For instance:

- NIH Project 5R01AI158463 (Infectious Disease Research Grant) could have produced novel insights into how SARS-CoV-2 develops resistance to antiviral drugs by investigating the mechanisms of its RNA replication complex.

Specifically, understanding the role of the nsp14 exonuclease and RNA polymerase regulation was expected to lead directly to novel therapeutic strategies effective against current and future coronavirus variants. Termination of funding prematurely ends this crucial research, limiting our ability to develop therapies capable of managing viral resistance.

- NIH Project 1P01AI165077-01 (PanCorVac – Center for Pan-Coronavirus Vaccine Development) aimed to develop broadly protective, protein-based vaccines against SARS-CoV-2 variants and other coronaviruses with potential to cause future pandemics. These studies were poised to deliver breakthroughs in vaccine efficacy and durability, significantly enhancing preparedness against a range of coronavirus threats.
- NIH Project 5R01MD018751 (Minority Health and Health Disparities Research Grant) could have resulted in scientific advancements in how to accurately capture the aspects of social support that are most beneficial and protective to individual and community mental health over time. With research-to-date finding that social support is linked to lower risk for all-cause mortality across populations, research from this terminated project could have provided critical information on how to leverage existing individual and community strategies for future intervention development, in turn reducing overall healthcare costs and strain.
- NIH Project P01HD109850 (Child Health and Human Development Extramural Research) could have provided pediatricians and youth-serving professionals with information needed to counsel families about media use and brain development.

Policymakers at the state and federal levels could have benefited from this in contemplating legislation regarding social media, smartphones, and other digital media use being debated across the country.

Conclusion

48. The breakdown in NIH processes is significantly affecting research, institutional operations, and planning. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Executed this 2nd day of April, 2025, in Madison, Wisconsin.

Dorota A. Grejner-Brzezinska, Ph.D.
Vice Chancellor for Research
University of Wisconsin-Madison

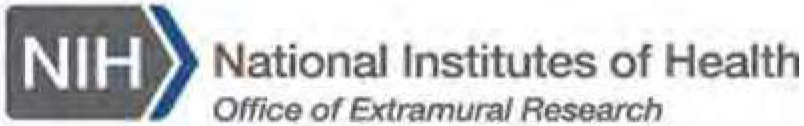
WI Decl. of Grejner-Brzezinska, Ex. A - 4.2.2025

Outlook

Grant Termination Notification

From Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Date Mon 3/24/2025 2:51 PM
To Nick Novak <nick.novak@wisc.edu>





3/24/2025

Nick Novak
University Of Wisconsin-Madison
nick.novak@wisc.edu

Dear Nick Novak:

Effective with the date of this letter, funding for Project Number 5R01AI158463-04 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 8/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Emily Linde, Chief Grants Management Officer, NIAID
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI158463
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
Robert N Kirchdoerfer, PHD
Assistant Professor
rnkirchdoerf@wisc.edu
608-262-6191

8. Authorized Official
Nick Novak
preaward@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Lindsey Ann Freeman

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
lindsey.kisliuk@nih.gov
301.761.6896

10. Program Official Contact Information
Mary Katherine Bradford Plimack

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
kate.plimack@nih.gov
(240) 447-9748

Federal Award Information

11. Award Number
5R01AI158463-04

12. Unique Federal Award Identification Number (FAIN)
R01AI158463

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Coronavirus RNA synthesis by multicomponent protein machines

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 08/01/2023 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$389,042
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$389,042
26. Project Period Start Date 08/05/2020 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,738,787

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI158463-04 REVISED

Principal Investigator(s):
Robert N Kirchdoerfer, PHD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI158463. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$92,144
Fringe Benefits	$19,327
Personnel Costs (Subtotal)	$111,471
Materials & Supplies	$40,000
Travel	$6,000
Other	$4,000
Publication Costs	$6,000
Equipment or Facility Rental/User Fees	$75,000
Tuition Remission	$12,000
Federal Direct Costs	$254,471
Federal F&A Costs	$134,571
Approved Budget	$389,042
Total Amount of Federal Funds Authorized (Federal Share)	$389,042
TOTAL FEDERAL AWARD AMOUNT	$389,042
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$389,042	$389,042

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: RAI158463ACV
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
AI	8056323	$389,042

NIH Administrative Data:
PCC: M51C B / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:04:46 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI158463-04 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI158463-04 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor

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should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI158463. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI158463-04 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Revised Award: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention

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

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

Supersedes previous Notice of Award dated **06/26/2024**. All other terms and conditions still apply to this award.

****

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the 04 year as agreed to in the correspondence dated **05/16/2024**. This is the only mid-project extension that will be allowed for the remainder of the project period.

This award also removes the no-cost extension authority of the NIH Standard Terms and Conditions of Award. NIAID prior approval is required to extend the project period end date for this award.

Supersedes previous Notice of Award dated **05/25/2023**. All other terms and conditions still apply to this award.

****

This award provides funds of $389,042 Total Costs ($254,471 Direct Costs and $134,571 F&A Costs) to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds provide support for the period 8/1/2023-7/31/2024. These funds are restricted to prevent, prepare for, and respond to coronavirus domestically or internationally only as described in the application submitted on 6/9/2020 and subsequent documentation submitted 5/10/2023, and may not be rebudgeted or used for any other purpose without NIAID prior approval.

***

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

***

Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

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If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.

If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI158463-04 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 4
Salaries and Wages	$92,144
Fringe Benefits	$19,327
Personnel Costs (Subtotal)	$111,471
Materials & Supplies	$40,000
Travel	$6,000
Other	$4,000
Publication Costs	$6,000
Equipment or Facility Rental/User Fees	$75,000
Tuition Remission	$12,000
TOTAL FEDERAL DC	$254,471
TOTAL FEDERAL F&A	$134,571
TOTAL COST	$389,042

Facilities and Administrative Costs	Year 4
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$242,471
F&A Costs 1	$134,571

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WI Decl. of Grejner-Brzezinska, Ex. B - 4.2.2025

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# P01AI165077
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
YOSHIHIRO KAWAOKA, DVM
Professor
yoshihiro.kawaoka@wisc.edu
608-265-4925

8. Authorized Official
Brenda Egan
nih@rsp.wisc.edu
608-262-3822

Federal Agency Information

9. Awarding Agency Contact Information
Elizabeth R. Sihombing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
elizabeth.sihombing@nih.gov
240-669-5530

10. Program Official Contact Information
JENNIFER L. Gordon
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jennifer.gordon2@nih.gov
3017616805

Federal Award Information

11. Award Number
1P01AI165077-01

12. Unique Federal Award Identification Number (FAIN)
P01AI165077

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
PanCorVac (Center for Pan-Coronavirus Vaccine Development)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/16/2021 **– End Date** 03/24/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$7,000,324
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$7,000,324
26. Project Period Start Date 09/16/2021 **– End Date** 03/24/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$7,000,324

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Emily Linde

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1P01AI165077-01 REVISED

Principal Investigator(s):
YOSHIHIRO KAWAOKA, DVM

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number P01AI165077. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Emily Linde
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
Travel	$59,250
Other	$100,000
Subawards/Consortium/Contractual Costs	$4,726,015
Publication Costs	$12,000
Federal Direct Costs	$6,170,370
Federal F&A Costs	$829,954
Approved Budget	$7,000,324
Total Amount of Federal Funds Authorized (Federal Share)	$7,000,324
TOTAL FEDERAL AWARD AMOUNT	$7,000,324
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$7,000,324	$7,000,324

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PAI165077AC6
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021
AI	8050485	$7,000,324

NIH Administrative Data:
PCC: M51Q S / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:01:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01AI165077-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1P01AI165077-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

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awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01AI165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1P01AI165077-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary. Therefore, this project is terminated.

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Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

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

Supersedes previous Notice of Award dated **08/30/2024**. All other terms and conditions still apply to this award.

*****

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the letter dated **07/30/2024**. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

This is the final extension that will be allowed for this project.

Supersedes previous Notice of Award dated **05/26/2023**. All other terms and conditions still apply to this award.

*****

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

REVISED AWARD: This award is revised to remove the requirement to submit an extension application for years four and five of the project period.

This Notice of Award removes carryover authority on this award.

Supersedes previous Notice of Award dated 09/17/2021. All other terms and conditions still apply to this award.

This award provides funds to prevent, prepare for, and respond to coronavirus, domestically or internationally. These funds are restricted for the emergency response to COVID-19 only and may not be rebudgeted or used for any other purpose without NIAID prior approval.

The budget period anniversary start date for future year(s) will be **September 1.**

This Notice of Award (NoA) includes funds for activity with **Georgia Tech Research Corporation** in the amount of **$1,404,775** (**$887,974** direct costs + **$516,801** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Chicago** in the amount of **$984,000** (**$600,000** direct costs + **$384,000** F&A costs).

This Notice of Award (NoA) includes funds for activity with **St. Jude Children's Research Hospital** in the amount of **$1,364,994** (**$749,997** direct costs + **$614,997** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$972,246** (**$573,597** direct costs + **$398,649** F&A costs).

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In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan
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This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the **Just-In-Time**. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

BEN-GURION UNIVERSITY OF THE NEGEV, ISRAEL

Duke-NUS Medical School, SINGAPORE

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used. When submitting future Progress Reports indicate at the beginning of the report:

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If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01AI165077-01 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1
Salaries and Wages	$656,967
Fringe Benefits	$221,196
Personnel Costs (Subtotal)	$878,163
Consultant Services	$60,000
Equipment	$23,942
Materials & Supplies	$311,000
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

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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WI Decl. of Grejner-Brzezinska, Ex. C - 4.2.2025



03/20/2025

Darlene Holte
UNIVERSITY OF WISCONSIN-MADISON
NIH@rsp.wisc.edu

Dear Darlene Holte:

Effective with the date of this letter, funding for Project Number 5R01MD018571-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 03/01/2025, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 12:18:35 -04'00'

Michelle G. Bulls, on behalf of Priscilla Grant, Chief Grants Management Officer, National Institute on Minority Health and Health Disparities
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Notice of Award
FAIN# R01MD018571
Federal Award Date
03/20/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
Elliot Tebbe, PHD (Contact)

tebbe@wisc.edu
320-339-9992

8. Authorized Official
Darlene Holte

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
shacklefords@mail.nih.gov
301-402-1366

10. Program Official Contact Information
Crystal Barksdale
Health Scientist Administrator/program Official
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
crystal.barksdale@nih.gov
301-402-1366

Federal Award Information

11. Award Number
5R01MD018571-02

12. Unique Federal Award Identification Number (FAIN)
R01MD018571

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A multidimensional investigation of social support for transgender and nonbinary people and its impacts on health and well-being: Measurement development using community engagement

15. Assistance Listing Number
93.307

16. Assistance Listing Program Title
Minority Health and Health Disparities Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2025 **– End Date** 03/20/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$681,042
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$681,042
26. Project Period Start Date 08/19/2024 **– End Date** 03/20/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,454,524

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5R01MD018571-02 REVISED

Principal Investigator(s):
Stephanie L Budge, PHD
Elliot Tebbe (contact), PHD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD018571. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Priscilla Grant
Grants Management Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$236,198
Fringe Benefits	$82,392
Personnel Costs (Subtotal)	$318,590
Consultant Services	$4,499
Materials & Supplies	$8,635
Travel	$7,290
Other	$81,383
Subawards/Consortium/Contractual Costs	$23,986
ADP/Computer Services	$180
Federal Direct Costs	$444,563
Federal F&A Costs	$236,479
Approved Budget	$681,042
Total Amount of Federal Funds Authorized (Federal Share)	$681,042
TOTAL FEDERAL AWARD AMOUNT	$681,042
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$681,042	$681,042

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	RMD018571A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
MD	8472687	$681,042

NIH Administrative Data:
PCC: CPS11 / **OC**: 41025 / **Released**: 03/20/2025
Award Processed: 03/21/2025 12:20:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MD018571-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01MD018571-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH

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awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01MD018571. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – MD SPECIFIC AWARD CONDITIONS – 5R01MD018571-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

INFORMATION: This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Therefore, this project is terminated. The

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University of Wisconsin-Madison may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), **as applicable**) within 120 days of the end of this grant.

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 2/18/2025 ALSO APPLY TO THIS AWARD:

INFORMATION: This non-competing award has been made at 90% of the level committed for FY2025. If the final appropriation permits, adjustments may be made up to the FY2025 funding plan level.

RESTRICTION: This program must not promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or any other protected characteristics.

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/2020, which is hereby incorporated by reference as special terms and conditions of this award.

Copies of this RFA may be accessed at the following internet address:
https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: Use of humans and animals in any new activities must be requested prior to the start of the activity and must be approved in writing in advance by the NIMHD. See NOT-MD-08-002, "Guidance and Clarification on NCMHD Policy on Prior Approval for Subprojects and Pilot Projects Involving Human Subjects or Vertebrate Animals," NIH Guide to Grants and Contracts, April 29, 2008, which is hereby incorporated by reference as special terms and conditions of this award. See also NOT-OD-15-129, "Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice," and NIH-OD-15-128, "Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice."

Copies of these Notices may be accessed at the following internet address:
http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

REQUIREMENT: The awardee is required to follow the Data Management and Sharing Plan included in the competing application and may not implement any changes in the plan without the written prior approval of the National Institute on Minority Health and Health Disparities.

INFORMATION: This award reflects the NIMHD's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension

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and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: Unobligated balances may be used by the NIMHD to reduce or offset funding for a subsequent budget period.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD018571-02 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 2
Salaries and Wages	$236,198
Fringe Benefits	$82,392
Personnel Costs (Subtotal)	$318,590
Consultant Services	$4,499
Materials & Supplies	$8,635
Travel	$7,290
Other	$81,383
Subawards/Consortium/Contractual Costs	$23,986
ADP/Computer Services	$180
TOTAL FEDERAL DC	$444,563
TOTAL FEDERAL F&A	$236,479
TOTAL COST	$681,042

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$426,088
F&A Costs 1	$236,479

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WI Decl. of Grejner-Brzezinska, Ex. D - 4.2.2025

Bulls, Michelle G. (NIH/OD) [E]
Christy Schulz
Grant Termination Notification
Friday, March 21, 2025 12:19:34 PM
image002.png



3/21/2025

Schulz, Christy R
University Of Wisconsin-Madison
crschulz@wisc.edu

Dear Schulz, Christy R:

Effective with the date of this letter, funding for Project Number 5P01HD109850-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10]

See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN
Branch Chief
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov
(301) 435-2307

Federal Award Information

11. Award Number
5P01HD109850-03

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,484,126
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,484,126
26. Project Period Start Date 09/12/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$4,567,357

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P01HD109850-03 REVISED

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
Federal Direct Costs	$995,547
Federal F&A Costs	$488,579
Approved Budget	$1,484,126
Total Amount of Federal Funds Authorized (Federal Share)	$1,484,126
TOTAL FEDERAL AWARD AMOUNT	$1,484,126
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,484,126	$1,484,126

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: PHD109850A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$1,484,126

NIH Administrative Data:
PCC: CDBB -CG / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:09:05 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P01HD109850-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5P01HD109850-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5P01HD109850-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, it is the policy of NIH not to prioritize such research programs.

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CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your

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position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

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NICHD 1% Reduction
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Notice of Funding Opportunity
This award is subject to the requirements indicated in **RFA-HD-22-009**, which are hereby incorporated by reference. See the NIH Funding site for more information.

Non-SNAP Type 5
NIH staff has determined that the submitted Research Performance Progress Report is within the approved scope of work.

Human Subjects
For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Subproject
Subproject funding information is available via the NIH RePORTER System.

SPREADSHEET SUMMARY
AWARD NUMBER: 5P01HD109850-03 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 3
Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
TOTAL FEDERAL DC	$995,547

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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EXHIBIT 30

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF MEGAN A. MORENO

I, Megan A. Moreno, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Department of Pediatrics Vice Chair of Academic Affairs in the University of Wisconsin–Madison (UW–Madison) School of Medicine and Public Health. I am a tenured Professor in the Department of Pediatrics. I am familiar with the facts and information in the statements set forth below, either through personal knowledge or in consultation with UW–Madison faculty.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I have been a Professor and Division Chief in the UW–Madison Department of Pediatrics since 2017 and have served as the Vice Chair of Academic Affairs for the Department since 2020. I am the co-medical director of the American Academy of Pediatrics (AAP) Center of Excellence: Creating a Healthy Digital Ecosystem for Children and Youth. I have served as a

reviewer for more than thirty academic journals in the fields of pediatrics, adolescent health, medical education, digital health, behavioral health, and public health; I currently serve as associate editor of *JAMA Pediatrics* and am an editorial board member for the *Journal of Adolescent Health*. I received my medical degree from George Washington University, a master of educational psychology degree from UW–Madison and a master of public health degree from the University of Washington. I have written a parenting handbook focused on healthy media use, as well as edited several textbooks on media and adolescent health. I have been honored to receive the AAP Council of Communications and Media's Holroyd-Sherry Award for Career Achievement (2020), an American Pediatrics Society Norman J. Siegel New Member Outstanding Science Award (2021–2022), and a Wisconsin Alumni Research Foundation Kellett Mid-Career Fellowship at UW–Madison (2021).

4. My research focuses on the intersection of technology and adolescent health. I am the principal investigator of the UW–Madison Social Media and Adolescent Health Research Team (SMAHRT). At SMAHRT, our research focuses on adolescent technology use and misuse, online safety, and social media influence on health behaviors. The National Institutes of Health ("NIH"), within the U.S. Department of Health and Human Services ("HHS") has been a key funder of SMAHRT's research going back more than fifteen years. I have had continuous federal funding as a principal investigator since the start of my faculty career, including funding from four NIH institutes (National Institute of Child Health and Human Development ["NICHD"], National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, and National Cancer Institute) and the U.S. Department of Justice. I served on the NIH Health, Behavior, and Context (CHHD-M) study section for six years. I am in the process of being onboarded to the NIH's National Advisory Child Health and Human Development (NACHHD)

Council and attended the January 2025 meeting. I have four pending NIH grant applications related to adolescent health, digital media and promoting healthy behaviors and, as further described below, one active (but purportedly terminated) NIH grant supporting SMAHRT and other research on campus investigating how technology and social media content relate to adolescent mental and behavioral health and wellbeing.

5. I am providing this declaration to detail my experience in applying for and reviewing NIH grant applications.

6. I am also providing this declaration to explain the impacts of grant terminations and delays in grant application review upon my staff, my research, and the people who benefit from it.

7. The terminations and delayed review of grant applications severely impacts me, SMAHRT, and other campus researchers and trainees. Full termination of my current NIH grant would have devastating impacts on our research teams, leading to profound layoffs among staff and trainees, including students. Moreover, it would squander taxpayer dollars invested in the projects thus far, and prevent pediatricians and youth-serving professionals from having the information they need to counsel families about media use and brain development. Additionally, delays in the review of my currently pending grant applications create uncertainty and disrupt the funding cycle necessary to maintain continuity of research projects and consistent staffing of trained researchers.

Reliance on NIH Funding

8. My current NIH award is a Research Program Grant (known as a P01), funded through a one-time Funding Opportunity Announcement titled, “Impact of Technology and Digital Media (TDM) Exposure/Usage on Child and Adolescent Development.” NIH P01s fund

broad, multidisciplinary, longitudinal research programs involving groups of investigators, each working on individual research projects supported by one or more research cores that contribute to the overall program objectives. My particular award supports two additional co-investigators on three independent projects with support from two campus research cores: Dr. Ellen Selkie, MD, MPH, Assistant Professor and Fellowship Program Director in the UW–Madison Department of Pediatrics; and Dr. Christopher Cascio, PhD, Associate Professor in the UW–Madison School of Journalism and Mass Communication.

9. This funding opportunity was highly competitive and intended to fund one award focused on adolescent health and media, and one focused on media use in young children. P01 funding opportunities are rare, and this particular call for applications was the first media-focused P01 at the NIH. We were awarded the P01 focused on adolescent health in this prestigious and first-of-its-kind funding opportunity. The program grant is titled, "A longitudinal study investigating TDM [technology and digital media] and adolescent health and development: Behavior, Neuroscience and Socioemotional Well-being." Our research program is the largest endeavor of its kind, having recruited over three hundred youth so far from across Wisconsin, with the goal of recruiting four hundred. The three projects encompassed by this grant all address a major health issue for Americans: the impact of media on adolescent physical and mental health, health behaviors, and brain development.

10. The P01 award provides salary support for the three faculty co-investigators (myself, 30%; Dr. Selkie, 40%; and Dr. Cascio, 42%). This significant salary support from the NIH creates protected time for each of us to not only conduct the research, but support undergraduate, graduate and post-doctoral trainees. All three investigators dedicate significant time to engage in mentoring and teaching of the trainees involved in the projects that comprise

this program. Further, Dr. Selkie is an assistant professor and early career faculty. She has received research training sponsored by NICHD funding through a K23 career development award, and participated in the NIH's Loan Repayment Program. Thanks to NIH's ongoing support of Dr. Selkie's career development she is able to lead one of the three projects that make up this P01.

11. Forty students — including undergraduate, graduate, and medical students — participate in the projects under this research program. They rely on NIH awards for Research and Project Assistant positions and summer support as they progress toward their degree. Loss of funding would disrupt graduate student data collection and support of secondary aims that were developed for dissertation research. This also impacts undergraduate educational opportunities in health research, potentially reducing the future STEM workforce in the U.S. The P01 also supports ten university staff who face reduced hours or layoffs without the funding. Finally, this P01 program grant involves several co-investigators from outside institutions, including from Texas, Ohio, Michigan and Pennsylvania, who will all lose the salary support and collaboration opportunities provided by this P01 grant if it is terminated.

Typical Timeline and Processes for NIH Grant Awards

12. For NIH grants, the first step in the process is typically a Notice of Funding Opportunity ("NOFO"), which may be a broad call for investigator-initiated proposals, or a more specific notice related to topics of emphasis. Some of these establish specific due dates, but for most there are standard deadlines based on the type of grant at issue. The standard due dates align with three annual review and funding cycles. For example, for research grants, the standard due dates fall in February, June, and October.

13. Grant applications are typically submitted via NIH's online portal, which also allows the applicant to track the status of the grant, and provides access to scores and summaries generated by study sections and advisory councils.

14. Study sections and advisory council meetings are typically scheduled to align with these three funding cycles, with numerous study sections held in each cycle prior to advisory council meetings.

15. In my previous experience as a reviewer on a study section, I was typically assigned 6-10 grants to review. This is an intensive and rigorous process, which typically takes 2-3 hours of my time for each grant in advance of the study section meeting. To be able to effectively present and discuss each of my assigned grants at the study section meeting, I typically need to conduct my review shortly before the meeting occurs. After reviewing the grant at the study section, we provide each with a score. This score, along with a summary statement that summarizes the discussion, is provided to the applicant and to the advisory council, which convenes to finalize funding decisions. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-to-5 year terms, though some may be longer and others may be shorter.

16. Although the life of the grant is often longer, funding is provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the stated project goals, in my experience such renewals are typically granted.

17. These regular cycles and predictable renewals are essential for the continuity of funding for my research team. In order to maintain staffing, I plan ahead for future grant submissions years in advance to ensure the end of one grant cycle is aligned with obtaining new grants. This reliable process is essential to maintaining a trained workforce within a research group and ensuring levels of staffing remain consistent and efficient. Further, the pursuit of new grants also allows our team to continue a line of research to its conclusion, as one project will answer a critical question that then leads to a next critical question. For example, if a project shows that a particular health intervention is effective and could be used in clinical settings, a subsequent project is needed to determine how to effectively scale and disseminate that new intervention.

18. In my experience, termination of an active grant is extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Delays and Irregularities in the Processing of NIH Grant Applications

19. Since late January 2025, I have seen an unusual number of delays in processing my grant applications, as well as in the grant review process in which I participate as a reviewer.

20. For example, in the past year I submitted four new grant applications, all of which remain pending. One grant was submitted in fall and scheduled for review in February 2025; however, this grant review was abruptly cancelled the week of the study section. In prior years, I would have expected to receive a score and summary statement on my applications by February 2025, and to have the advisory committee meeting for the current cycle occur in June. Based on scores or outcomes, this would have left me with time to prepare new applications, or address

issued raised and resubmit this application for funding this year. However, this year, the study section review was inexplicably delayed, and only this past week was rescheduled for late April. I have not received any formal communication explaining the delay.

21. In the past, I have consistently received timely scores and communications from NIH regarding my applications.

22. In my role as a division chief and vice chair in the Department of Pediatrics, I provide mentoring and supervision of faculty who also serve on study sections. Through this work, I have learned that at a March 2025 study section, reviewers were directed to "refrain from evaluating, scoring, or incorporating diversity, equity, and inclusion into the final scoring. Additionally, kindly avoid mentioning these terms in your critiques." During the study section meeting, multiple section members were interrupted when speaking and told by NIH staff to refrain from use of these terms. Two weeks before the study section, two grants were suddenly removed from review "while NIH undertakes a review of its research priorities under NIH's statutory and regulatory authorities." NIH staff have told faculty in our department that future grants related to gender identity will not be accepted. These new approaches do not align with the priorities of child health, scientific merit, and processes that have served the NIH since its inception.

23. As an incoming member of the NAACHD council, I completed the onboarding process, which included extensive background checks, orientation meetings, and taking the Oath of Office. I learned that in this role, I would receive a list of grants with scores and summary statements generated by numerous study sections reviewing grants for NICHD. These are ranked by the advisory council, and a list of grants recommended for funding is generated. I attended an initial meeting and observed these highly rigorous, transparent processes in action. However, in

early February I was informed that they were unable to complete the certification for any new Advisory Council members, and that I and other new members would remain in a holding pattern. This delay, uncertainty, and wasted time in the onboarding process for all involved is unprecedented, inefficient, and has no benefits.

Irregularities in Grant Terminations

24. We recently received a letter from NIH purporting to terminate the P01 grant referenced in paragraph 8 above because it does not "effectuate agency priorities."

25. NIH initially issued our award on September 12, 2022, with an anticipated total budget of $7.57 million (~$1.5 million per year) for a term of five years. Initial Notice of Award (Sept. 12, 2022), attached hereto as Exhibit A. As of the date the grant was terminated, UW–Madison had drawn $3.51 million, with an anticipated additional disbursement of $4.06 million over the next 2.5 years.

26. On March 21, 2025 the university received a Grant Termination Notification via email from Michelle Bulls, Director of the NIH Office of Policy for Extramural Research Administration. Email from Michelle G. Bulls to Christy Schulz (Mar. 21, 2025), attached hereto as Exhibit B. This was followed by a new Notice of Award (NOA), dated March 25, 2025, confirming termination and directing the university on closeout procedures. Terminating Notice of Award (Mar. 25, 2025), attached hereto as Exhibit C. Both the email and the NOA provided only the following explanation for why the award no longer "effectuates agency priorities": "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." Beyond this assertion, NIH did not include any explanation on what

those new agency priorities are, or why our research program specifically no longer furthers those priorities. I was not referred to any new policy statement or regulation that described the new agency priorities, and efforts to obtain further clarification from NIH were unsuccessful, seemingly due to staffing reductions and changes at NIH. Our Program Officer's position was terminated in February 2025. The next Program Officer assigned to our program grant retired ten days after the termination email was received, so we were unable to meet with or gain any clarifying information from him. As of the date of this declaration, we do not know who our Program Officer is, and have not received any communication from the new Acting Branch Chief.

27. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that the NICHD's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Specifically, our research program is funded under the Child Health and Human Development Extramural Research Assistance Listing Program, which – as of the date of this declaration – was last updated on February 27, 2025. SAM.gov Assistance Listing Directory Search Results (Apr. 1, 2025), attached hereto as Exhibit D. The Assistance Listing description of fiscal year 2025 funding projects indicates that, "[r]esearch on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth." SAM.gov Child Health and Human Development Extramural Research Assistance Listing (Apr. 1, 2025), attached hereto as Exhibit E. Additionally, in a March 20, 2025 interview, HHS Secretary Robert F. Kennedy, Jr. stated that, among children, "social media use on cellphones has been directly

connected with depression, with poor performance in schools, with suicidal ideation, with substance abuse," highlighting it as a particular area of concern for the Department. Fox and Friends, *RFK Jr. launches investigation into 'high levels' of heavy metals in baby formula* (Mar. 20, 2025, 8:48 AM) https://www.foxnews.com/video/6370269070112.

28. Our research program advances the above goals in several ways. This project focuses on the impact of media on brain development, health behaviors, and media's influence on healthy and risky behaviors, and how media impacts socioemotional development. The data, if collected, would give us the unique opportunity to examine the effects of digital and social media use over time, in contrast to studies that only include a single time point, and which have failed to answer important questions about the relationship between social media use and change in health outcomes. We would determine, through longitudinal data, the impact of social media use on the developing brain of adolescents. We would also understand how adolescents share information about health and risk behaviors (such as physical activity, sleep, and alcohol use) on social media, and are influenced by content about those behaviors. Finally, we would leverage our data to provide information and resources to teens and families about specific social media behaviors and actions that may enhance well-being and mental health. Families across the country are aware of and concerned about media's impact on mental health, as well as physical health, including obesity and sleep. Pediatricians struggle to provide accurate information to parents because the impact of media on children's development, including brain development and impact on behavior, is not known. All three projects in this program grant are designed to fill this gap in understanding. A critical part of this work is to give back to the local communities across Wisconsin and to provide new insight into the impacts of digital and social media on

youth and families. These insights are also critical for healthcare providers, educators, policymakers, and community members, and a range of other stakeholders

29. The March 21, 2025 Notice of Termination email also stated the following: "Although 'NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,' no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Exhibit B, quoting NIH Grants Policy Statement at IIA-156. To the extent NIH is asserting that corrective action is impossible because the premise of the entire research program is "based on gender identity," NIH provides no information supporting that assertion, and it is incorrect. Of the three projects under this award, one aim of one project includes a comparison of sexual and gender minority youth and non-sexual gender minority youth with respect to social media engagement to understand different strategies and impacts of technology and digital media on wellbeing between these groups. However, at no point was the university contacted by the Program Official, Grants Management Officer, or any other representative of NIH to share NIH's concern about the scope of the research program or discuss possible modifications. With so much time, funding, and other resources already invested in the program, terminating now without apparently even considering modification feels particularly wasteful.

Comparisons Across Administrations

30. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses and awards. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

31. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my and other UW–Madison faculty communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

32. Due to the termination, delays and funding uncertainty, my lab will be forced to: suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts; terminate employment of research staff, who will be forced to seek other employment; and stop ongoing data collection in this longitudinal study, compromising time-sensitive components of the research. Interruption of data collection in a longitudinal study puts all of the work of the research team and the participants to waste if the full study data is not completed.

33. If this grant is terminated, the three faculty co-investigators will no longer have the salary support that creates protected time for research and student mentoring. Undergraduate students working on projects funded by this P01 rely on the research program to obtain required experience to pursue master's degrees, PhDs, and MDs. These students are likely to change career course if they cannot build the necessary experiences to gain admission to post-graduate programs. Graduate students and post-doctoral trainees who rely on research conducted within our P01 to obtain their PhDs are likely to see years of delay in their progression and career development as a result of termination.

34. With termination of NIH funding, Dr. Selkie's research and faculty career will be significantly and negatively impacted, including risks to her overall research program and faculty trajectory. Prior NIH-funded training for her scientific career (as detailed above) will have been squandered.

35. Finally, this P01 termination also impacts the families who have committed to being part of this project. Parents have driven their adolescents across the state for MRI appointments, and youth have shared information about their social media use with us over months and years. This termination would put all of the work of those participants and their families to waste. It would also squander the taxpayer dollars that had supported it thus far because halting the study during the longitudinal data collection dashes our chances of observing the temporal relationships between social media use and outcomes that so many other studies were not designed to address. This termination would also prevent pediatricians and youth-serving professionals from having the information they need to counsel families about media use and brain development. Policymakers at the state and federal levels would also benefit from this data as they contemplate legislation regarding social media, smartphones, and other digital media use being debated across the country.

36. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

37. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure

talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

Executed this 2nd day of April, 2025, in Madison, Wisconsin.

/s/ Megan A. Moreno
Megan A. Moreno
Professor, Vice Chair of Academic Affairs
Department of Pediatrics
University of Wisconsin–Madison

WI Decl. of Moreno, Ex. A
4.2.2025

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
09-12-2022

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301

MADISON, 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov

Federal Award Information

11. Award Number
1P01HD109850-01

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-12-2022 **– End Date** 08-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$1,580,159
20 a. Direct Cost Amount	$1,025,587
20 b. Indirect Cost Amount	$554,572
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,580,159
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,580,159
26. Project Period Start Date 09-12-2022 **– End Date** 08-31-2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,580,159

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Sarah M Lee

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(301) 435-2307

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1P01HD109850-01

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,580,159 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Sarah M Lee
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$548,938
Fringe Benefits	$186,212
Personnel Costs (Subtotal)	$735,150
Consultant Services	$21,000
Materials & Supplies	$14,000
Travel	$18,000
Other	$109,050
Subawards/Consortium/Contractual Costs	$98,387
Publication Costs	$10,000
ADP/Computer Services	$2,000
Tuition Remission	$18,000

Federal Direct Costs	$1,025,587
Federal F&A Costs	$554,572
Approved Budget	$1,580,159
Total Amount of Federal Funds Authorized (Federal Share)	$1,580,159
TOTAL FEDERAL AWARD AMOUNT	$1,580,159
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,580,159

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$1,580,159	$1,580,159
2	$1,503,072	$1,503,072
3	$1,499,116	$1,499,116
4	$1,491,340	$1,491,340
5	$1,497,560	$1,497,560

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1396006492A1
Document Number:	PHD109850A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025	2026
HD	8014702	$1,580,159	$1,503,072	$1,499,116	$1,491,340	$1,497,560

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -JG / **OC**: 41021 / **Released**: Lee, Sarah 09-01-2022
Award Processed: 09/12/2022 12:07:16 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1P01HD109850-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

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SECTION III – STANDARD TERMS AND CONDITIONS – 1P01HD109850-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

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In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1P01HD109850-01

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to NICHD notification to the recipient that the identified issues have been resolved and this restriction is removed.

The verification of IRB approval must be submitted no later than **November 30, 2022**, to the Grants Management Specialist indicated on this Notice of Award. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

Delayed Start Date

This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **September 1.**

Escalation

In accordance with the NICHD FY2022 fiscal policy, escalation on recurring costs has been removed.

Salary CAP

No award funds shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See NIH Guide Notice NOT-OD-22-076.

Subproject

Subproject funding information is available via the NIH RePORTER System.

Overlap

This award is contingent upon the adjustment in Dr. Ellen M. Selkie's effort as described in the updated Other Support/JIT dated 08/01/2022.

Human Subjects

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 “NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research”. All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical

trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

Beginning January 2021, for all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

COVID-19

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. Please contact the Grants Management Specialist and Program Official indicated on this Notice of Award for more information.

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01HD109850-01

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$548,938	$548,938	$559,818	$559,817	$559,817
Fringe Benefits	$186,212	$186,212	$190,347	$190,347	$190,347
Personnel Costs (Subtotal)	$735,150	$735,150	$750,165	$750,164	$750,164
Consultant Services	$21,000	$21,000	$13,000	$13,000	$13,000
Materials & Supplies	$14,000	$14,000	$6,000	$6,000	$6,000
Travel	$18,000	$18,000	$18,000	$18,000	$18,000
Other	$109,050	$88,050	$90,050	$85,050	$89,050
Subawards/Consortium/Contractual Costs	$98,387	$98,387	$98,387	$98,387	$98,387
Publication Costs	$10,000	$10,000	$10,000	$10,000	$10,000
ADP/Computer Services	$2,000	$2,000	$2,000	$2,000	$2,000
Tuition Remission	$18,000	$18,000	$18,000	$18,000	$18,000
TOTAL FEDERAL DC	$1,025,587	$1,004,587	$1,005,602	$1,000,601	$1,004,601
TOTAL FEDERAL F&A	$554,572	$498,485	$493,514	$490,739	$492,959
TOTAL COST	$1,580,159	$1,503,072	$1,499,116	$1,491,340	$1,497,560

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	55.5%	55.5%	55.5%	55.5%	55.5%
F&A Cost Base 1	$999,228	$898,172	$889,215	$884,214	$888,214
F&A Costs 1	$554,572	$498,485	$493,514	$490,739	$492,959

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WI Decl. of Moreno, Ex. B
4.2.2025

From: Bulls, Michelle G. (NIH/OD) [E]
To: Christy Schulz
Subject: Grant Termination Notification
Date: Friday, March 21, 2025 12:19:34 PM
Attachments: image002.png



3/21/2025

Schulz, Christy R
University Of Wisconsin-Madison
crschulz@wisc.edu

Dear Schulz, Christy R:

Effective with the date of this letter, funding for Project Number 5P01HD109850-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7]

Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer, NICHD
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10]

See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

WI Decl. of Moreno, Ex. C
4.2.2025

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# P01HD109850
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF WISCONSIN SYSTEM
21 N PARK ST STE 6301
MADISON, WI 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

7. Project Director or Principal Investigator
MEGAN A. MORENO, MD
Professor Of Pediatrics
mamoreno@pediatrics.wisc.edu
608-263-2846

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

9. Awarding Agency Contact Information
Sarah M Lee
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
SARAH.LEE@NIH.GOV
(240) 276-6280

10. Program Official Contact Information
JAMES GRIFFIN
Branch Chief
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
griffinj@mail.nih.gov
(301) 435-2307

Federal Award Information

11. Award Number
5P01HD109850-03

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A longitudinal study investigating TDM and adolescent health and development: Brain, Behavior and well-Being

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,484,126
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,484,126
26. Project Period Start Date 09/12/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$4,567,357

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

RESEARCH PROGRAM PROJECT
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P01HD109850-03 REVISED

Principal Investigator(s):
MEGAN A. MORENO, MD

Award e-mailed to: NIH@rsp.wisc.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF WISCONSIN-MADISON in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number P01HD109850. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

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Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
Federal Direct Costs	$995,547
Federal F&A Costs	$488,579
Approved Budget	$1,484,126
Total Amount of Federal Funds Authorized (Federal Share)	$1,484,126
TOTAL FEDERAL AWARD AMOUNT	$1,484,126
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,484,126	$1,484,126

Fiscal Information:
Payment System Identifier: 1396006492A1
Document Number: PHD109850A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$1,484,126

NIH Administrative Data:
PCC: CDBB -CG / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:09:05 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5P01HD109850-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5P01HD109850-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the

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definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) P01HD109850. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

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NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5P01HD109850-03 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, it is the policy of NIH not to prioritize such research programs.

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CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your

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position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

****

NICHD 1% Reduction
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Notice of Funding Opportunity
This award is subject to the requirements indicated in **RFA-HD-22-009**, which are hereby incorporated by reference. See the NIH Funding site for more information.

Non-SNAP Type 5
NIH staff has determined that the submitted Research Performance Progress Report is within the approved scope of work.

Human Subjects
For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

Subproject
Subproject funding information is available via the NIH RePORTER System.

SPREADSHEET SUMMARY
AWARD NUMBER: 5P01HD109850-03 REVISED

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

Budget	Year 3
Salaries and Wages	$554,220
Fringe Benefits	$188,444
Personnel Costs (Subtotal)	$742,664
Consultant Services	$12,870
Materials & Supplies	$5,940
Travel	$17,820
Other	$89,150
Subawards/Consortium/Contractual Costs	$97,403
Publication Costs	$9,900
ADP/Computer Services	$1,980
Tuition Remission	$17,820
TOTAL FEDERAL DC	$995,547

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TOTAL FEDERAL F&A	$488,579
TOTAL COST	$1,484,126

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$880,323
F&A Costs 1	$488,579

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- ◉ All Words
- ○ Exact Phrase

e.g. 64.106

93.865 ×

Dates

Federal Organizations

Eligibility

Assistance Type

Location

Status

- [x] Active
- [ ] Inactive

Reset

Federal Assistance | **Assistance Listings** | **Subaward Reports**

Sort by

Last Updated Date: New - Old

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93.865 Child Health and Human Development Extramural Research

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human dev...

Dept / Ind Agency: HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier: NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Feb 27, 2025

Type of Assistance
B-Cooperative Agreements (Discretionary Grants), B-Project Grants

93.361 Nursing Research

Nurses understand that improving health and well-being means addressing people's needs in multiple settings, contexts, and over the whole life course....

Dept / Ind Agency: HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier: NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Nov 18, 2024

Type of Assistance
B-Cooperative Agreements, M-Training, B-Project Grants

93.977 Sexually Transmitted Diseases (STD) Prevention and Control Grants

The purpose of the assistance is to strengthen STD prevention programs in eligible jurisdictions. Project grants awarded under Section 318 to State an...

Assistance Listing

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

93.978 Sexually Transmitted Diseases (STD) Provider Education Grants

Assistance Listing

The purpose of the assistance is to fund academic institutions and clinical and public health training organizations to develop, deliver and evaluate ...

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

93.286 Discovery and Applied Research for Technological Innovations to Improve Human Health

Assistance Listing

To support hypothesis-, design-, technology-, or device-driven research related to the discovery, design, development, validation, and application of ...

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

Last Updated Date
Nov 11, 2024

Type of Assistance
B-Cooperative Agreements (Discretionary Grants), B-Project Grants (Discretionary)

+ History

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ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing
Overview
Authorizations
Financial Information
Criteria for Applying
Applying for Assistance
Compliance Requirements
Contact Information
History

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

View available opportunities on Grants.gov related to this Assistance Listing

Overview

Objectives

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

Examples of Funded Projects

Fiscal Year 2024: The NICHD program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. Most U.S. women will be affected by one or more gynecological disorders during their lifetime. NICHD manages a broad research portfolio to better understand, treat, and prevent these common, painful, and costly conditions, including endometriosis, uterine fibroids, Polycystic Ovary Syndrome, chronic pelvic pain, and pelvic floor disorders. Uterine fibroids are the most common non-cancerous tumors in women and can cause pain and abnormal bleeding. Sometimes fibroids can make it difficult for a woman to become pregnant or maintain a pregnancy. NICHD-supported scientists are working to develop new prevention and treatment approaches. For example, researchers found that a treatment featuring the drug relugolix could help reduce heavy menstrual bleeding and pain associated with fibroids, without loss in bone mineral density. Another research team is looking at a different drug, an anti-inflammatory medication, which reduced the size of fibroid tumors in mice without side effects. Endometriosis is another gynecologic health condition that can cause severe pain, irregular periods, and infertility. Although the condition runs in families, known genes explain less than two percent of cases. To identify more genes that can account for the condition, researchers recently combined the data from two dozen studies that looked at the whole genomes of almost 61,000 women who had endometriosis, as well as another 702,000 who did not. The scientists found 42 locations within the women's DNA that were linked to endometriosis. A closer look revealed genetic connections to 11 pain conditions, such as migraine, headache, back and spinal pain, and multisite chronic pain. Future studies that reveal more about the shared biology between the pain and inflammatory conditions and endometriosis could lead to new therapies. There is an urgent need for safe, effective, and less invasive infertility treatments, as well as contraception options for both men and women. With support from NICHD, male contraceptive agents are already being tested in humans, and even more promising approaches are being developed in animal models. In a mouse study, researchers identified a potential non-hormonal contraceptive compound that could be taken shortly before sexual activity, with fertility restored the very next day. A recently discovered gene expressed only in the reproductive organs is another promising target for male contraception, because deactivating this gene does not appear to interfere with testosterone production and would not block the hormone's other functions, such as regulating sex drive, building bone mass, and muscle strength. As NIH's leader in pregnancy and maternal health research, NICHD supports studies on clinical treatments

to reduce the risk of pregnancy complications for both pregnant women and their offspring. Through NIH's IMPROVE initiative, NICHD established Maternal Health Research Centers of Excellence to develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity across the country. These Centers, comprising 10 research centers, a data innovation and coordinating hub and an implementation science hub. Together, these institutions will work to design and implement research projects to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. They will focus on populations that experience health disparities, including racial and ethnic minorities, socioeconomically disadvantaged populations, those living in underserved rural areas, sexual and gender minority populations and people with disabilities. The IMPROVE initiative also includes two Challenge prize competition initiatives, in addition to traditional grant funding, that provide innovative approaches to well defined barriers in maternal health care and research engagement. The Rapid Acceleration of Diagnostics (RADx® Tech) for Maternal Health Challenge leverages an innovation funnel approach to accelerate the development of maternal health diagnostic or other remote-sensing technologies (e.g., wearable devices, smartphone-enabled tools) to improve access to care in the postpartum period and complement the use of telehealth in areas without sufficient maternity care. The Connecting the Community for Maternal Health Challenge aims to address the structural barriers faced by community and advocacy organizations to conduct maternal health research by helping them build effective research infrastructure and capacity.

Fiscal Year 2025: NICHD continues to improve understanding of the effects of COVID-19 infection and disease during pregnancy, in the postpartum, during lactation, and in newborns, as well as its long term impact, and continues to work toward inclusion of pregnant and lactating people in SARS-CoV-2 vaccine research. A recent study found that by late 2022, widespread COVID-19 vaccination of pregnant people likely halted a spike in the preterm birth rate that began at the start of the pandemic. Another study found that preterm infants receive similar levels of maternal antibody protection as term infants after maternal COVID-19 vaccination. NICHD's research networks play a leading role in clinical research advances for maternal and neonatal health. For example, in a large, multi-country clinical trial, researchers showed that a single dose of the antibiotic azithromycin can reduce the risk of postpartum sepsis and death by one third among women who deliver vaginally. For vulnerable infants, scientists found that extremely preterm infants who were fed fortified human milk grew longer and more rapidly and had larger head circumferences compared with extremely preterm infants fed unfortified human milk. The findings provide support for future studies on the potential benefits of human milk fortification in preventing malnutrition among infants born at 28 weeks or younger. NICHD is represented on the executive and steering committees of the NIH-wide Climate Change and Health Initiative aiming to reduce the health threats posed by climate change across the lifespan. The health effects of climate and environmental changes can affect many stages of a women's reproductive life,

impacting the health of future generations. Growing evidence suggests that heat stress negatively influences fetal growth and pregnancy outcomes, as two recent studies from NICHD's Global Network for Women's and Children's Health illustrate. One study, which evaluated more than 120,000 pregnant women in India and Pakistan, found a higher incidence of pregnancy-related high blood pressure, severe preeclampsia, preterm birth, and low birth weight with greater temperatures. Another study, conducted in Pakistan, found that exposure to excessive heat in early pregnancy was linked to lower infant lengths and head circumferences at birth. The findings also suggest that nutritional supplementation early in pregnancy may help offset some of the effects of heat stress. Research on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth. This research program also supports the evidence base for pediatric medicine, through clinical studies in pharmacology, infectious diseases, endocrinology, trauma and critical illness, and other aspects of health throughout infancy, childhood, and adolescence. Although children have distinct medical needs, and their physiology is not the same as adults, medical practices are often extrapolated from adult research without adequate study specifically in children. The Collaborative Pediatric Critical Care Research Network is funded by NICHD to conduct large-scale, multicenter randomized controlled trials to provide the research needed to make the best medical decisions for children in real-time while they are in the pediatric intensive care unit. Recent research supported through NICHD uncovered links between severe sepsis—a factor in 60 percent of child deaths worldwide—and certain genes related to the child's immune system. These findings are opening the way for genetic screening to tailor sepsis treatment according to a child's specific immune system functioning. NICHD also administers eight grants to refine technologies for early diagnosis of severe illnesses resulting from SARS-CoV-2 infection in children, including Multisystem Inflammatory Syndrome in Children (MIS-C). NICHD-supported researchers recently found that children with COVID-19 who develop MIS-C have unique biochemical indicators of cell injury and cell death, providing a pathway to develop tests that can identify children with MIS-C. Other researchers identified the mechanism by which MIS-C appears to cause shock in children. Inflammation of the blood vessels prevents the vessels from constricting, resulting in low blood pressure and circulation. This finding indicates that medications that constrict the blood vessels may be a preferred treatment option. NICHD supports a broad spectrum of research that seeks to prevent and treat pediatric injuries. To minimize the impact of head injury in youth football, researchers compared the magnitude, frequency, and location of head impacts among youth and college football players to inform the development of age-appropriate guidelines for helmet design and other prevention measures.

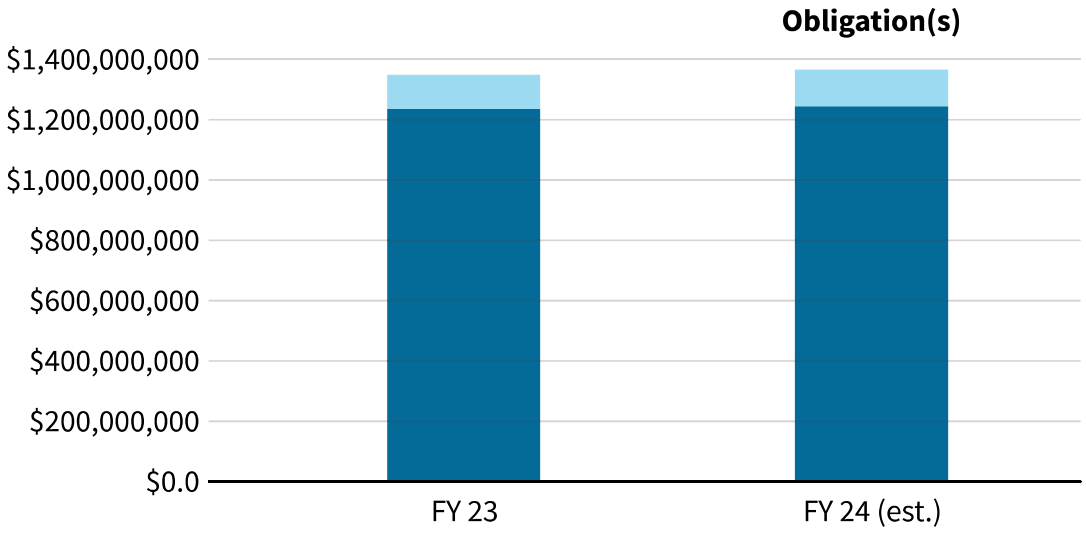
Authorizations

Public Health Service Act, Section 301, 448 and 487, as amended, Public Laws 78-410 and 99-158, as amended, 42 U.S.C. 241; 42 U.S.C. 285g; 42 U.S.C. 288; Small Business

Research and Development Enhancement Act of 1992, Public Law 102-564, Public Law 118-47

Financial Information

These funding amounts do not reflect the award amounts that are displayed on USASpending.gov



Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
☐ **Project Grants Total**	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**
For FY 2023, of the $1,233,369,249 for Total Research Grants, $51,684,492 was for SBIR/STTR activities and awards. For FY 2024, of the $1,241,888,972 for Total Research Grants, $51,395,322 was for SBIR/STTR activities and awards. For FY 2025, of the estimated $1,247,152,000 for Total Research Grants, $51,136,000 is planned for SBIR/STTR activities and awards. NOTE: these amounts	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**

Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
do not include training, R&D contracts of operating funds.			
☐ Cooperative Agreements (Discretionary Grants) Total	**$111,889,797**	**$120,423,704**	**$120,500,000**
Totals	**$1,345,259,046**	**$1,362,312,676**	**$1,367,652,000**

Range and Average of Financial Assistance

For research project grants, fiscal year 2024, range is $50,000 to $5,000,000; average is $534,606. Individual research fellowship awards: Basic stipend (first year beyond the doctoral degree) of approximately $45,000. The sponsoring institution will be provided, on application, with an allowance of up to approximately $8,000 per year to help defray the cost of training. No dependency allowances. SBIR: Average Phase I awards are for approximately $225,000 (grant activity R43 - for up to six months); Phase II awards may be made for amounts up to $1,500,000 (grant activity R44 - for up to two years).

Accomplishments

Fiscal Year 2024: Budget Actuals: Fiscal year 2024 competing and noncompeting research project grants actuals are 1,839. Of this number, 70 were SBIR/ STTR awards. Exactly 61 research centers were awarded. Exactly 423 other research grants were awarded. There were institutional training grants to support 389 trainees that were awarded in fiscal year 2024. The individual training award were 292 for fiscal year 2024.

Fiscal Year 2025: Budget Request: Fiscal year 2025 planned competing and noncompeting research project grants are expected to be 1,859. Of this number, 89 are planned to be SBIR/ STTR awards. An estimated 66 research centers are planned to be awarded. There are plans for 411 other research grants to be awarded. There are plans for institutional training grants to support 409 trainees to be awarded in fiscal year 2025. The individual training awards are estimated at 299 for fiscal year 2025.

Account Identification

75-0844-0-1-552-DHHS/NIH/ Eunice Kennedy Shriver National Institute

Criteria for Applying

Types of Assistance

B - Project Grants, B - Cooperative Agreements (Discretionary Grants)

Credentials and Documentation

Applicants should submit electronically via Grants.gov as directed in the relevant NIH Funding Opportunity Announcement. All required forms specified in the application kit are to be completed by the applicant and submitted with the application package. National Research Service Award: Individual Award: The applicant's academic record, research experience, citizenship, and institution sponsorship should be documented in the application. Institutional Award: the applicant organization must show the objectives, methodology, and resources for the research training program, the qualifications and experience of directing staff, the criteria to be used in selecting individuals for awards, and a detailed budget and justification for the amount of grant funds requested. For-profit organizations' costs are determined in accordance with 48 CFR, Subpart 31.2 of the Federal Acquisition Regulations. For other grantees, costs will be determined by HHS Regulations, 45 CFR, Part 74, Subpart Q. For SBIR and STTR grants, applicant organization (small business concern) must present in a research plan an idea that has potential for commercialization and furnish evidence that scientific competence, experimental methods, facilities, equipment, and funds requested are appropriate to carry out the plan. 2 CFR 200, Subpart E - Cost Principles applies to this program.

Applicant Eligibility

Designations

State (includes District of Columbia, public institutions of higher education and hospitals), Local (includes State-designated lndian Tribes, excludes institutions of higher education and hospitals, Public nonprofit institution/organization (includes institutions of higher education and hospitals), Individual/Family, Private nonprofit institution/organization (includes institutions of higher education and hospitals)

Universities, colleges, medical, dental and nursing schools, schools of public health, laboratories, hospitals, State and local health departments, other public or private institutions, both nonprofit and for-profit, and individuals. National Research Service Award: Support is provided for academic and research training only, in health and

health-related areas that are periodically specified by the National Institutes of Health. Individuals with a professional or scientific degree are eligible (M.D., Ph.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree). Predoctoral research training grants to institutions are also supported. Proposed study must result in biomedical or behavioral research training in a specified shortage area and which may offer opportunity to research health scientists, research clinicians, etc., to broaden their scientific background or to extend their potential for research in health-related areas. Applicants must be citizens of the United States or be admitted to the United States for permanent residency; they also must be nominated and sponsored by a public or private institution having staff and facilities suitable to the proposed research training. Domestic nonprofit organizations may apply for the institutional NRS grant. SBIR: SBIR grants can be awarded only to domestic small businesses (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed, and have no more than 500 employees). Primary employment (more than one- half time) of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In both Phase I and Phase II, the research must be performed in the U.S. or its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council. STTR grants can be awarded only to domestic small business concerns (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed and have no more than 500 employees) which "partner" with a research institution in cooperative research and development. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent by the research institution. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council.

Beneficiary Eligibility

Designations

Individual/Family, Private nonprofit institution/organization, Student/Trainee, Scientist/Researchers, State, U.S. Citizen, Local, Public nonprofit institution/organization

Any nonprofit or for-profit organization, company, or institution engaged in biomedical or biobehavioral research.

Length and Time Phasing of Assistance

Awards are usually made annually with no project period to exceed 5 years in length. National Research Service Awards: From 1 to 3 years. SBIR: Phase I awards are generally for 6 months; Phase II awards normally may not exceed 2 years. STTR Phase I awards are generally for 1 year; Phase II awards normally may not exceed 2 years. Method of awarding/releasing assistance: Each year, submitted progress reports for awarded grants are reviewed, and if satisfactory progress is demonstrated, a Notice of Grant Award is issued.

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

Grantee agrees to administer the grant in accordance with the regulations and policies governing the research grant programs of the Public Health Service as stated in the terms and conditions on the application for the grant. National Research Service Awards: Awarded to individuals for full-time research training in specified behavioral and biomedical shortage areas. Awardees may utilize some of their time in academic and clinical duties if such work is closely related to their research training. Awards may be made to institutions to enable them to make NRS awards to individuals selected by them. Each individual awardee is obligated upon termination of the award to comply with certain service and payback provisions. SBIR Phase I grants (of approximately 6-months' duration) are to establish the technical merit and feasibility of a proposed research effort that may lead to a commercial product or process. Phase II grants are for the continuation of the research initiated in Phase I and which are likely to result in commercial products or processes. STTR Phase I grants (normally of 1- year duration) are to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort that has potential for commercial application. Phase II funding is based on results of research initiated in Phase I and scientific and technical merit and commercial potential on Phase II application.

Applying for Assistance

Deadlines

Contact the headquarters or regional location, as appropriate for application deadlines

Preapplication Coordination

Preapplication coordination is not applicable. Environmental impact information is not required for this program. This program is excluded from coverage under E.O. 12372.

Application Procedures

2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards applies to this program.
National Research Service Award: Prior to formal application, an individual must arrange for acceptance at a sponsoring institution by a sponsor who will supervise the training. Individuals must be sponsored by a domestic or foreign institution. SBIR/STTR: Same as for grants (above). Applications are submitted electronically via Grants.gov following the general guidance provided at: http://grants.nih.gov/grants/forms.htm and the specific instructions for the respective Funding Opportunities Announcement which may be found at: https://grants.nih.gov/funding/index.htm

Criteria for Selecting Proposals

The major elements in evaluating proposals include assessments of the significance of the proposed research; approach; innovation; investigators; and environment. The following criteria will be used in considering the scientific and technical merit of SBIR/STTR Phase I grant applications: (1) The soundness and technical merit of the proposed approach; (2) the qualifications of the proposed principal investigator, supporting staff, and consultants; (3) the technological innovation of the proposed research; (4) the potential of the proposed research for commercial application; (5) the appropriateness of the budget requested; (6) the adequacy and suitability of the facilities and research environment; and (7) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment. Phase II grant applications will be reviewed based upon the following criteria: (1) The degree to which the Phase I objectives were met and feasibility demonstrated; (2) the scientific and technical merit of the proposed approach for achieving the Phase II objectives; (3) the qualifications of the proposed principal investigator, supporting staff, and consultants; (4) the technological innovation originality, or societal importance of the proposed research; (5) the potential of the proposed research for commercial application; (6) the reasonableness of the budget requested for the work proposed; (7) the adequacy and suitability of the facilities and research environment; and (8) where applicable, the adequacy of (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment.

Award Procedure

Each application receives a dual scientific review by non-NIH scientists. Awards are issued by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). National Research Service Awards: Applications are reviewed for scientific merit by an appropriate study section committee or by an institute review committee. If recommended for approval and a decision is made to make an award, a formal award notice will be sent to the applicant and sponsor. Institutional Awards are issued by the Eunice Kenney Shriver National Institute of Child Health and Human Development (NICHD). All accepted SBIR/STTR applications are evaluated for scientific and technical merit by an appropriate scientific peer review panel and by a national advisory council or board. All applications receiving a priority score compete for the available SBIR/STTR set-aside funds on the basis of scientific and technical merit and the commercial potential of the proposed research, program relevance, and program balance among the areas of research. Contact the headquarters or regional office, as appropriate, for application deadlines, or consult the specific Funding Opportunity Announcement listed in the NIH Guide for Grants and Contracts at: https://grants.nih.gov/funding/searchGuide/nih-guide-to-grants-and-contracts.cfm. General guidance about application due dates may be found at: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Date Range for Approval/Disapproval

> 180 Days. From 6 to 9 months: National Research Service Awards: From 6 to 9 months. SBIR/STTR: approximately 6 months.

Renewals

> 180 Days. Renewal applications are accepted, as described in the relevant Funding Opportunity Announcement (FOA) found at: http://grants.nih.gov/grants/guide/index.html?CFID=50541572&CFTOKEN=87322295&jsessionid=f630f3b44e23db8088b9e5e522459636127 National Research Service Awards: awards may be made for 1, 2, or 3 years. No individual may receive NIH fellowship support at the postdoctoral level for more than 3 years. Institutional Awards may be renewed.

Appeals

Not Applicable. A principal investigator (P.I.) may question the substantive or procedural aspects of the review of his/her application by communicating with the staff of the Institute. A description of the NIH Peer Review Appeal procedures is available on the NIH

web site at:
http://public.csr.nih.gov/ApplicantResources/InitialReviewResultsAppeals/Pages/default.as

Compliance Requirements

Policy Requirements

The following 2CFR policy requirements apply to this assistance listing:
Subpart B, General provisions

Subpart C, Pre-Federal Award Requirements and Contents of Federal Awards

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

The following 2CFR policy requirements are excluded from coverage under this assistance listing:
Not Applicable

Additional Information:

Reports

Program Reports: NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than

the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions. Grantees are allowed a specified period of time to submit required financial and final progress reports (see 45 CFR parts 74.51 and 74.52, 92.40 and 92.41, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

Cash Reports: The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic grantees this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS. For awards issued to foreign institutions after October 1, 2012, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in PMS using subaccounts and payments will be specific to each grant at the time the grantee draws funds.

Progress Reports: Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation (e.g., Research Performance Progress Report [RPPR]) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information. NIH continues to transition to using the RPPR for progress reporting. The RPPR is a federal wide format for the submission of required annual or other interim performance reporting on grant and cooperative agreement awards. The transition to RPPR will be implemented in phases through a module in the eRA Commons. The RPPR is now required for all SNAP and fellowship awards. The PHS 2590 non-competing continuation progress report is currently required for all other NIH awards; however, the RPPR will eventually replace the PHS 2590 paper progress report.

Expenditure Reports: Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. NIH requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons Federal Financial Report (FFR) system allows

participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports. Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. An annual FFR is required for awards to foreign organizations made prior to October 1, 2012 and Federal institutions made prior to October 1, 2013, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date. In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR.

Performance Reports: The grantee institution is required to submit a progress report on an annual basis for each grant award, which includes monitoring of performance.

Audits

Refer to the link below for 2 CFR Subpart F Audit Requirements.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-F
Additional audit requirements:

In addition, grants and cooperative agreements are subject to inspection and audits by DHHS and other Federal officials.

Records

Expenditures and other financial records must be retained for 3 years from the day on which the grantee submits the last expenditure report for the report period.

Regulations, Guidelines, and Literature

42 CFR 52; 42 CFR 66; 45 CFR 74; 45 CFR 92; NIH Grants Policy Statement, (Rev.) March 1, 2001, available on the NIH website at http://grants.nih.gov/grants/policy/nihgps_2001/; NIH Guide to Grants and Contracts, available on the NIH website at http://grants.nih.gov/grants/guide/. Grants will be available under the authority of and administered in accordance with the NIH Grants Policy Statement and Federal regulations at 42 CFR 52 and 42 USC 241; Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant and Cooperative Agreement Applications. Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer (STTR) Grant Applications.

Formula and Matching Requirements

Statutory formula is not applicable to this assistance listing.
Matching requirements are not applicable to this assistance listing.
MOE requirements are not applicable to this assistance listing.

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

Rebekah S. Rasooly, PhD
Director, Division of Extramural Activities DHHS/NIH/NICHD/DEA 6710B Rockledge Drive, Bethesda, MD 20892-7510
rebekah.rasooly@nih.gov
301-827-2599
Website: https://www.nichd.nih.gov/grants-contracts/process-strategies

History

2025
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2022
Published
Child Health and Human Development Extramural Research

2021
Published
Child Health and Human Development Extramural Research

2020
Published
Child Health and Human Development Extramural Research

2019
Published
Child Health and Human Development Extramural Research

2018
Published
Child Health and Human Development Extramural Research

2004
Title Changed
Child Health and Human Development Extramural Research

1998
Title Changed
Center for Research for Mothers and Children

1990
Number Changed
Number changed from 13.865

-
Published
Research for Mothers and Children

Feedback

Accessibility Contact

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SAM.gov

An official website of the U.S. General Services Administration

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Subaward Reporting is live on SAM.gov Show Details
Mar 8, 2025

Scheduled SAM Maintenance Show Details
Mar 18, 2025

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ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing
Overview
Authorizations
Financial Information
Criteria for Applying
Applying for Assistance
Compliance Requirements
Contact Information
History

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

View available opportunities on Grants.gov related to this Assistance Listing

Overview

Objectives

The Eunice Kennedy Shriver National Institute of Child Health and Human Development's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

Examples of Funded Projects

Fiscal Year 2024: The NICHD program in reproductive health, pregnancy, and perinatology supports basic, clinical, and translational research on gynecologic and andrologic disorders; contraception; fertility and infertility; pregnancy; and newborn care. Most U.S. women will be affected by one or more gynecological disorders during their lifetime. NICHD manages a broad research portfolio to better understand, treat, and prevent these common, painful, and costly conditions, including endometriosis, uterine fibroids, Polycystic Ovary Syndrome, chronic pelvic pain, and pelvic floor disorders. Uterine fibroids are the most common non-cancerous tumors in women and can cause pain and abnormal bleeding. Sometimes fibroids can make it difficult for a woman to become pregnant or maintain a pregnancy. NICHD-supported scientists are working to develop new prevention and treatment approaches. For example, researchers found that a treatment featuring the drug relugolix could help reduce heavy menstrual bleeding and pain associated with fibroids, without loss in bone mineral density. Another research team is looking at a different drug, an anti-inflammatory medication, which reduced the size of fibroid tumors in mice without side effects. Endometriosis is another gynecologic health condition that can cause severe pain, irregular periods, and infertility. Although the condition runs in families, known genes explain less than two percent of cases. To identify more genes that can account for the condition, researchers recently combined the data from two dozen studies that looked at the whole genomes of almost 61,000 women who had endometriosis, as well as another 702,000 who did not. The scientists found 42 locations within the women's DNA that were linked to endometriosis. A closer look revealed genetic connections to 11 pain conditions, such as migraine, headache, back and spinal pain, and multisite chronic pain. Future studies that reveal more about the shared biology between the pain and inflammatory conditions and endometriosis could lead to new therapies. There is an urgent need for safe, effective, and less invasive infertility treatments, as well as contraception options for both men and women. With support from NICHD, male contraceptive agents are already being tested in humans, and even more promising approaches are being developed in animal models. In a mouse study, researchers identified a potential non-hormonal contraceptive compound that could be taken shortly before sexual activity, with fertility restored the very next day. A recently discovered gene expressed only in the reproductive organs is another promising target for male contraception, because deactivating this gene does not appear to interfere with testosterone production and would not block the hormone's other functions, such as regulating sex drive, building bone mass, and muscle strength. As NIH's leader in pregnancy and maternal health research, NICHD supports studies on clinical treatments

to reduce the risk of pregnancy complications for both pregnant women and their offspring. Through NIH's IMPROVE initiative, NICHD established Maternal Health Research Centers of Excellence to develop and evaluate innovative approaches to reduce pregnancy-related complications and deaths and promote maternal health equity across the country. These Centers, comprising 10 research centers, a data innovation and coordinating hub and an implementation science hub. Together, these institutions will work to design and implement research projects to address the biological, behavioral, environmental, sociocultural, and structural factors that affect pregnancy-related complications and deaths. They will focus on populations that experience health disparities, including racial and ethnic minorities, socioeconomically disadvantaged populations, those living in underserved rural areas, sexual and gender minority populations and people with disabilities. The IMPROVE initiative also includes two Challenge prize competition initiatives, in addition to traditional grant funding, that provide innovative approaches to well defined barriers in maternal health care and research engagement. The Rapid Acceleration of Diagnostics (RADx® Tech) for Maternal Health Challenge leverages an innovation funnel approach to accelerate the development of maternal health diagnostic or other remote-sensing technologies (e.g., wearable devices, smartphone-enabled tools) to improve access to care in the postpartum period and complement the use of telehealth in areas without sufficient maternity care. The Connecting the Community for Maternal Health Challenge aims to address the structural barriers faced by community and advocacy organizations to conduct maternal health research by helping them build effective research infrastructure and capacity.

Fiscal Year 2025: NICHD continues to improve understanding of the effects of COVID-19 infection and disease during pregnancy, in the postpartum, during lactation, and in newborns, as well as its long term impact, and continues to work toward inclusion of pregnant and lactating people in SARS-CoV-2 vaccine research. A recent study found that by late 2022, widespread COVID-19 vaccination of pregnant people likely halted a spike in the preterm birth rate that began at the start of the pandemic. Another study found that preterm infants receive similar levels of maternal antibody protection as term infants after maternal COVID-19 vaccination. NICHD's research networks play a leading role in clinical research advances for maternal and neonatal health. For example, in a large, multi-country clinical trial, researchers showed that a single dose of the antibiotic azithromycin can reduce the risk of postpartum sepsis and death by one third among women who deliver vaginally. For vulnerable infants, scientists found that extremely preterm infants who were fed fortified human milk grew longer and more rapidly and had larger head circumferences compared with extremely preterm infants fed unfortified human milk. The findings provide support for future studies on the potential benefits of human milk fortification in preventing malnutrition among infants born at 28 weeks or younger. NICHD is represented on the executive and steering committees of the NIH-wide Climate Change and Health Initiative aiming to reduce the health threats posed by climate change across the lifespan. The health effects of climate and environmental changes can affect many stages of a women's reproductive life,

impacting the health of future generations. Growing evidence suggests that heat stress negatively influences fetal growth and pregnancy outcomes, as two recent studies from NICHD's Global Network for Women's and Children's Health illustrate. One study, which evaluated more than 120,000 pregnant women in India and Pakistan, found a higher incidence of pregnancy-related high blood pressure, severe preeclampsia, preterm birth, and low birth weight with greater temperatures. Another study, conducted in Pakistan, found that exposure to excessive heat in early pregnancy was linked to lower infant lengths and head circumferences at birth. The findings also suggest that nutritional supplementation early in pregnancy may help offset some of the effects of heat stress. Research on child and adolescent health encompasses biological and behavioral processes that control development, including development of social-emotional health, cognitive development, learning, and physical growth. This research program also supports the evidence base for pediatric medicine, through clinical studies in pharmacology, infectious diseases, endocrinology, trauma and critical illness, and other aspects of health throughout infancy, childhood, and adolescence. Although children have distinct medical needs, and their physiology is not the same as adults, medical practices are often extrapolated from adult research without adequate study specifically in children. The Collaborative Pediatric Critical Care Research Network is funded by NICHD to conduct large-scale, multicenter randomized controlled trials to provide the research needed to make the best medical decisions for children in real-time while they are in the pediatric intensive care unit. Recent research supported through NICHD uncovered links between severe sepsis—a factor in 60 percent of child deaths worldwide—and certain genes related to the child's immune system. These findings are opening the way for genetic screening to tailor sepsis treatment according to a child's specific immune system functioning. NICHD also administers eight grants to refine technologies for early diagnosis of severe illnesses resulting from SARS-CoV-2 infection in children, including Multisystem Inflammatory Syndrome in Children (MIS-C). NICHD-supported researchers recently found that children with COVID-19 who develop MIS-C have unique biochemical indicators of cell injury and cell death, providing a pathway to develop tests that can identify children with MIS-C. Other researchers identified the mechanism by which MIS-C appears to cause shock in children. Inflammation of the blood vessels prevents the vessels from constricting, resulting in low blood pressure and circulation. This finding indicates that medications that constrict the blood vessels may be a preferred treatment option. NICHD supports a broad spectrum of research that seeks to prevent and treat pediatric injuries. To minimize the impact of head injury in youth football, researchers compared the magnitude, frequency, and location of head impacts among youth and college football players to inform the development of age-appropriate guidelines for helmet design and other prevention measures.

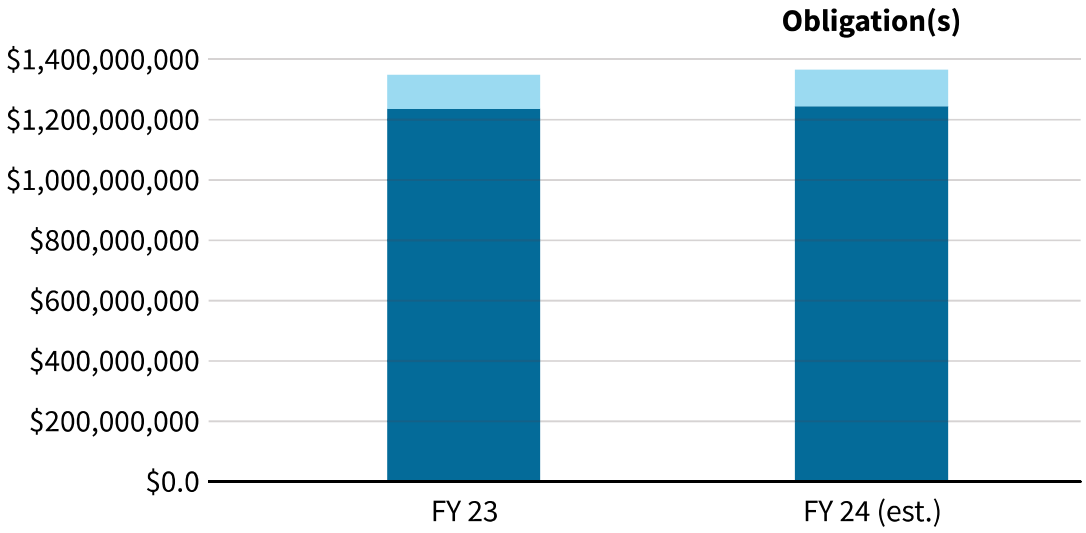
Authorizations

Public Health Service Act, Section 301, 448 and 487, as amended, Public Laws 78-410 and 99-158, as amended, 42 U.S.C. 241; 42 U.S.C. 285g; 42 U.S.C. 288; Small Business

Research and Development Enhancement Act of 1992, Public Law 102-564, Public Law 118-47

Financial Information

These funding amounts do not reflect the award amounts that are displayed on USASpending.gov



Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
☐ **Project Grants Total**	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**
For FY 2023, of the $1,233,369,249 for Total Research Grants, $51,684,492 was for SBIR/STTR activities and awards. For FY 2024, of the $1,241,888,972 for Total Research Grants, $51,395,322 was for SBIR/STTR activities and awards. For FY 2025, of the estimated $1,247,152,000 for Total Research Grants, $51,136,000 is planned for SBIR/STTR activities and awards. NOTE: these amounts	**$1,233,369,249**	**$1,241,888,972**	**$1,247,152,000**

Obligation(s)	FY 23	FY 24 (est.)	FY 25 (est.)
do not include training, R&D contracts of operating funds.			
☐ Cooperative Agreements (Discretionary Grants) Total	**$111,889,797**	**$120,423,704**	**$120,500,000**
Totals	**$1,345,259,046**	**$1,362,312,676**	**$1,367,652,000**

Range and Average of Financial Assistance

For research project grants, fiscal year 2024, range is $50,000 to $5,000,000; average is $534,606. Individual research fellowship awards: Basic stipend (first year beyond the doctoral degree) of approximately $45,000. The sponsoring institution will be provided, on application, with an allowance of up to approximately $8,000 per year to help defray the cost of training. No dependency allowances. SBIR: Average Phase I awards are for approximately $225,000 (grant activity R43 - for up to six months); Phase II awards may be made for amounts up to $1,500,000 (grant activity R44 - for up to two years).

Accomplishments

Fiscal Year 2024: Budget Actuals: Fiscal year 2024 competing and noncompeting research project grants actuals are 1,839. Of this number, 70 were SBIR/ STTR awards. Exactly 61 research centers were awarded. Exactly 423 other research grants were awarded. There were institutional training grants to support 389 trainees that were awarded in fiscal year 2024. The individual training award were 292 for fiscal year 2024.

Fiscal Year 2025: Budget Request: Fiscal year 2025 planned competing and noncompeting research project grants are expected to be 1,859. Of this number, 89 are planned to be SBIR/ STTR awards. An estimated 66 research centers are planned to be awarded. There are plans for 411 other research grants to be awarded. There are plans for institutional training grants to support 409 trainees to be awarded in fiscal year 2025. The individual training awards are estimated at 299 for fiscal year 2025.

Account Identification

75-0844-0-1-552-DHHS/NIH/ Eunice Kennedy Shriver National Institute

Criteria for Applying

Types of Assistance

B - Project Grants, B - Cooperative Agreements (Discretionary Grants)

Credentials and Documentation

Applicants should submit electronically via Grants.gov as directed in the relevant NIH Funding Opportunity Announcement. All required forms specified in the application kit are to be completed by the applicant and submitted with the application package. National Research Service Award: Individual Award: The applicant's academic record, research experience, citizenship, and institution sponsorship should be documented in the application. Institutional Award: the applicant organization must show the objectives, methodology, and resources for the research training program, the qualifications and experience of directing staff, the criteria to be used in selecting individuals for awards, and a detailed budget and justification for the amount of grant funds requested. For-profit organizations' costs are determined in accordance with 48 CFR, Subpart 31.2 of the Federal Acquisition Regulations. For other grantees, costs will be determined by HHS Regulations, 45 CFR, Part 74, Subpart Q. For SBIR and STTR grants, applicant organization (small business concern) must present in a research plan an idea that has potential for commercialization and furnish evidence that scientific competence, experimental methods, facilities, equipment, and funds requested are appropriate to carry out the plan. 2 CFR 200, Subpart E - Cost Principles applies to this program.

Applicant Eligibility

Designations

State (includes District of Columbia, public institutions of higher education and hospitals), Local (includes State-designated lndian Tribes, excludes institutions of higher education and hospitals, Public nonprofit institution/organization (includes institutions of higher education and hospitals), Individual/Family, Private nonprofit institution/organization (includes institutions of higher education and hospitals)

Universities, colleges, medical, dental and nursing schools, schools of public health, laboratories, hospitals, State and local health departments, other public or private institutions, both nonprofit and for-profit, and individuals. National Research Service Award: Support is provided for academic and research training only, in health and

health-related areas that are periodically specified by the National Institutes of Health. Individuals with a professional or scientific degree are eligible (M.D., Ph.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree). Predoctoral research training grants to institutions are also supported. Proposed study must result in biomedical or behavioral research training in a specified shortage area and which may offer opportunity to research health scientists, research clinicians, etc., to broaden their scientific background or to extend their potential for research in health-related areas. Applicants must be citizens of the United States or be admitted to the United States for permanent residency; they also must be nominated and sponsored by a public or private institution having staff and facilities suitable to the proposed research training. Domestic nonprofit organizations may apply for the institutional NRS grant. SBIR: SBIR grants can be awarded only to domestic small businesses (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed, and have no more than 500 employees). Primary employment (more than one- half time) of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In both Phase I and Phase II, the research must be performed in the U.S. or its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council. STTR grants can be awarded only to domestic small business concerns (entities that are independently owned and operated for profit, are not dominant in the field in which research is proposed and have no more than 500 employees) which "partner" with a research institution in cooperative research and development. At least 40 percent of the project is to be performed by the small business concern and at least 30 percent by the research institution. In both Phase I and Phase II, the research must be performed in the U.S. and its possessions. To be eligible for funding, a grant application must be approved for scientific merit and program relevance by a scientific review group and a national advisory council.

Beneficiary Eligibility

Designations

Individual/Family, Private nonprofit institution/organization, Student/Trainee, Scientist/Researchers, State, U.S. Citizen, Local, Public nonprofit institution/organization

Any nonprofit or for-profit organization, company, or institution engaged in biomedical or biobehavioral research.

Length and Time Phasing of Assistance

Awards are usually made annually with no project period to exceed 5 years in length. National Research Service Awards: From 1 to 3 years. SBIR: Phase I awards are generally for 6 months; Phase II awards normally may not exceed 2 years. STTR Phase I awards are generally for 1 year; Phase II awards normally may not exceed 2 years. Method of awarding/releasing assistance: Each year, submitted progress reports for awarded grants are reviewed, and if satisfactory progress is demonstrated, a Notice of Grant Award is issued.

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

Grantee agrees to administer the grant in accordance with the regulations and policies governing the research grant programs of the Public Health Service as stated in the terms and conditions on the application for the grant. National Research Service Awards: Awarded to individuals for full-time research training in specified behavioral and biomedical shortage areas. Awardees may utilize some of their time in academic and clinical duties if such work is closely related to their research training. Awards may be made to institutions to enable them to make NRS awards to individuals selected by them. Each individual awardee is obligated upon termination of the award to comply with certain service and payback provisions. SBIR Phase I grants (of approximately 6-months' duration) are to establish the technical merit and feasibility of a proposed research effort that may lead to a commercial product or process. Phase II grants are for the continuation of the research initiated in Phase I and which are likely to result in commercial products or processes. STTR Phase I grants (normally of 1- year duration) are to determine the scientific, technical, and commercial merit and feasibility of the proposed cooperative effort that has potential for commercial application. Phase II funding is based on results of research initiated in Phase I and scientific and technical merit and commercial potential on Phase II application.

Applying for Assistance

Deadlines

Contact the headquarters or regional location, as appropriate for application deadlines

Preapplication Coordination

Preapplication coordination is not applicable. Environmental impact information is not required for this program. This program is excluded from coverage under E.O. 12372.

Application Procedures

2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards applies to this program.
National Research Service Award: Prior to formal application, an individual must arrange for acceptance at a sponsoring institution by a sponsor who will supervise the training. Individuals must be sponsored by a domestic or foreign institution. SBIR/STTR: Same as for grants (above). Applications are submitted electronically via Grants.gov following the general guidance provided at: http://grants.nih.gov/grants/forms.htm and the specific instructions for the respective Funding Opportunities Announcement which may be found at: https://grants.nih.gov/funding/index.htm

Criteria for Selecting Proposals

The major elements in evaluating proposals include assessments of the significance of the proposed research; approach; innovation; investigators; and environment. The following criteria will be used in considering the scientific and technical merit of SBIR/STTR Phase I grant applications: (1) The soundness and technical merit of the proposed approach; (2) the qualifications of the proposed principal investigator, supporting staff, and consultants; (3) the technological innovation of the proposed research; (4) the potential of the proposed research for commercial application; (5) the appropriateness of the budget requested; (6) the adequacy and suitability of the facilities and research environment; and (7) where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment. Phase II grant applications will be reviewed based upon the following criteria: (1) The degree to which the Phase I objectives were met and feasibility demonstrated; (2) the scientific and technical merit of the proposed approach for achieving the Phase II objectives; (3) the qualifications of the proposed principal investigator, supporting staff, and consultants; (4) the technological innovation originality, or societal importance of the proposed research; (5) the potential of the proposed research for commercial application; (6) the reasonableness of the budget requested for the work proposed; (7) the adequacy and suitability of the facilities and research environment; and (8) where applicable, the adequacy of (a) safeguarding human or animal subjects, and/or (b) protecting against or minimizing any adverse effect on the environment.

Award Procedure

Each application receives a dual scientific review by non-NIH scientists. Awards are issued by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). National Research Service Awards: Applications are reviewed for scientific merit by an appropriate study section committee or by an institute review committee. If recommended for approval and a decision is made to make an award, a formal award notice will be sent to the applicant and sponsor. Institutional Awards are issued by the Eunice Kenney Shriver National Institute of Child Health and Human Development (NICHD). All accepted SBIR/STTR applications are evaluated for scientific and technical merit by an appropriate scientific peer review panel and by a national advisory council or board. All applications receiving a priority score compete for the available SBIR/STTR set-aside funds on the basis of scientific and technical merit and the commercial potential of the proposed research, program relevance, and program balance among the areas of research. Contact the headquarters or regional office, as appropriate, for application deadlines, or consult the specific Funding Opportunity Announcement listed in the NIH Guide for Grants and Contracts at: https://grants.nih.gov/funding/searchGuide/nih-guide-to-grants-and-contracts.cfm. General guidance about application due dates may be found at: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Date Range for Approval/Disapproval

> 180 Days. From 6 to 9 months: National Research Service Awards: From 6 to 9 months. SBIR/STTR: approximately 6 months.

Renewals

> 180 Days. Renewal applications are accepted, as described in the relevant Funding Opportunity Announcement (FOA) found at: http://grants.nih.gov/grants/guide/index.html?CFID=50541572&CFTOKEN=87322295&jsessionid=f630f3b44e23db8088b9e5e522459636127 National Research Service Awards: awards may be made for 1, 2, or 3 years. No individual may receive NIH fellowship support at the postdoctoral level for more than 3 years. Institutional Awards may be renewed.

Appeals

Not Applicable. A principal investigator (P.I.) may question the substantive or procedural aspects of the review of his/her application by communicating with the staff of the Institute. A description of the NIH Peer Review Appeal procedures is available on the NIH

web site at:
http://public.csr.nih.gov/ApplicantResources/InitialReviewResultsAppeals/Pages/default.as

Compliance Requirements

Policy Requirements

The following 2CFR policy requirements apply to this assistance listing:
Subpart B, General provisions

Subpart C, Pre-Federal Award Requirements and Contents of Federal Awards

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

The following 2CFR policy requirements are excluded from coverage under this assistance listing:
Not Applicable

Additional Information:

Reports

Program Reports: NIH requires that grantees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), and specialized programmatic reports. Grantees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities, as specified in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. The GMO is the official receipt point for most required reports. However, NIH has centralized the submission of annual progress reports; details are provided below. In addition, electronic submission through the eRA Commons is required for some annual progress reports and available for all closeout documents (final grant progress reports, final invention statements and certifications, and final financial status reports). When a paper non-competing continuation progress report is submitted, only a signed original is required; no copies are required. Submission of these reports to an address other than

the centralized one may result in delays in processing of the non-competing continuation award or the submission being considered delinquent. FFRs must be electronically submitted to OFM (see Financial Reports below) through the eRA Commons eFFR feature unless otherwise indicated in the award's terms and conditions. Grantees are allowed a specified period of time to submit required financial and final progress reports (see 45 CFR parts 74.51 and 74.52, 92.40 and 92.41, and the discussion in this subsection). Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions, including withholding, removal of certain NIH Standard Terms of Award, or conversion to a reimbursement payment method (also see Administrative Requirements—Enforcement Actions). The schedule for submission of the non-competing continuation progress report is discussed in the next subsection.

Cash Reports: The FFR has a dedicated section to report Federal cash receipts and disbursements. For domestic grantees this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS. For awards issued to foreign institutions after October 1, 2012, even though payment is now through PMS, the requirement for quarterly cash reporting does not apply. These awards are now administered in PMS using subaccounts and payments will be specific to each grant at the time the grantee draws funds.

Progress Reports: Progress reports usually are required annually as part of the non-competing continuation award process. NIH may require these reports more frequently. The "Non-Competing Continuation Progress Report" (PHS 2590) or equivalent documentation (e.g., Research Performance Progress Report [RPPR]) must be submitted to, and approved by, NIH to non-competitively fund each additional budget period within a previously approved project period (competitive segment). Except for awards subject to SNAP, the progress report includes an updated budget in addition to other required information. NIH continues to transition to using the RPPR for progress reporting. The RPPR is a federal wide format for the submission of required annual or other interim performance reporting on grant and cooperative agreement awards. The transition to RPPR will be implemented in phases through a module in the eRA Commons. The RPPR is now required for all SNAP and fellowship awards. The PHS 2590 non-competing continuation progress report is currently required for all other NIH awards; however, the RPPR will eventually replace the PHS 2590 paper progress report.

Expenditure Reports: Reports of expenditures are required as documentation of the financial status of grants according to the official accounting records of the grantee organization. NIH requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR) system located in the eRA Commons. This includes all initial FFRs being prepared for submission and any revised FSR/FFRs being submitted or re-submitted to NIH. The eRA Commons Federal Financial Report (FFR) system allows

participants to view information on currently due and late expenditure reports and to submit these reports electronically to NIH. Paper expenditure reports are not accepted. Expenditure data submitted to NIH is initially reviewed and accepted by OFM. NIH IC grants management staff also review these expenditure reports. Except for awards under SNAP and awards that require more frequent reporting, the FFR is required on an annual basis. An annual FFR is required for awards to foreign organizations made prior to October 1, 2012 and Federal institutions made prior to October 1, 2013, whether or not they are under SNAP. When required on an annual basis, the report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. Failure to submit timely reports may affect future funding. The report also must cover any authorized extension in time of the budget period. If more frequent reporting is required, the NoA will specify both the frequency and due date. In lieu of the annual FFR expenditure data, NIH will monitor the financial aspects of grants under SNAP by using the information submitted directly to PMS. The GMO may review the report for patterns of cash expenditures, including accelerated or delayed drawdowns, and to assess whether performance or financial management problems exist. For these SNAP awards, FFR expenditure data is required only at the end of a competitive segment. It must be submitted within 90 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment. An FFR must be submitted at this time whether or not a competing continuation award is made. If no further award is made, this report will serve as the final FFR.

Performance Reports: The grantee institution is required to submit a progress report on an annual basis for each grant award, which includes monitoring of performance.

Audits

Refer to the link below for 2 CFR Subpart F Audit Requirements.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-F
Additional audit requirements:

In addition, grants and cooperative agreements are subject to inspection and audits by DHHS and other Federal officials.

Records

Expenditures and other financial records must be retained for 3 years from the day on which the grantee submits the last expenditure report for the report period.

Regulations, Guidelines, and Literature

42 CFR 52; 42 CFR 66; 45 CFR 74; 45 CFR 92; NIH Grants Policy Statement, (Rev.) March 1, 2001, available on the NIH website at http://grants.nih.gov/grants/policy/nihgps_2001/; NIH Guide to Grants and Contracts, available on the NIH website at http://grants.nih.gov/grants/guide/. Grants will be available under the authority of and administered in accordance with the NIH Grants Policy Statement and Federal regulations at 42 CFR 52 and 42 USC 241; Omnibus Solicitation of the Public Health Service for Small Business Innovation Research (SBIR) Grant and Cooperative Agreement Applications. Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer (STTR) Grant Applications.

Formula and Matching Requirements

Statutory formula is not applicable to this assistance listing.
Matching requirements are not applicable to this assistance listing.
MOE requirements are not applicable to this assistance listing.

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

Rebekah S. Rasooly, PhD
Director, Division of Extramural Activities DHHS/NIH/NICHD/DEA 6710B Rockledge Drive, Bethesda, MD 20892-7510
rebekah.rasooly@nih.gov
301-827-2599
Website: https://www.nichd.nih.gov/grants-contracts/process-strategies

History

2025
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2022
Published
Child Health and Human Development Extramural Research

2021
Published
Child Health and Human Development Extramural Research

2020
Published
Child Health and Human Development Extramural Research

2019
Published
Child Health and Human Development Extramural Research

2018
Published
Child Health and Human Development Extramural Research

2004
Title Changed
Child Health and Human Development Extramural Research

1998
Title Changed
Center for Research for Mothers and Children

1990
Number Changed
Number changed from 13.865

-
Published
Research for Mothers and Children

Feedback

Our Website

About This Site
Our Community
Release Notes
System Alerts

Policies

Terms of Use
Privacy Policy
Restricted Data Use
Freedom of Information Act

Our Partners

Acquisition.gov
USASpending.gov
Grants.gov
More Partners

Customer Service

Help
Check Entity Status
Federal Service Desk
External Resources

Accessibility Contact

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SAM.gov

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EXHIBIT 31

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF PRIYA NAMBISAN

I, Priya Nambisan, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a Associate Professor at the University of Wisconsin-Milwaukee. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am an Associate Professor at the University of Wisconsin-Milwaukee with 20 years of experience in academia. I previously held roles in three other higher education institutions – UAlbany, SUNY, and George Mason University. I have a Master's Degree in nutrition from Syracuse University and PhD in Communication from Rensselaer Polytechnic Institute and did a one year post-doc in Health Informatics at University of Wisconsin-Madison.

4. I lead two laboratories - one focused on Social media and health called SMAHRT (Social Media And Health Research & Training) lab and another one focused on older adults and technology called ARDT (Aging Research & Digital Technologies) lab at University of Wisconsin – Milwaukee. I have served as a Principal Investigator (PI) or Co-Investigator on numerous funded projects over the course of my career. I also currently serve on NIH small business SBIR/STTR study section, which is a study section focused on technological innovations for improving minority health and eliminating health disparities.

5. I am providing this declaration to detail my experience with terminations of NIH-funded grants historically, and how that experience has changed since late January of 2025.

6. I am also providing this declaration to explain the impacts of delays in the grant review and renewal process and of grant terminations on my staff, my research, and the people who benefit from it.

7. The termination severely impacts my research and my lab, specifically my SMAHRT lab, as much of the work done by students and hourly pay staff had to be stopped. Social media's impact on mental health of adolescents and youth is an important, time critical and relevant topic for research. Terminating our study could limit our ability to develop appropriate interventions to mitigate the negative impact of social media use on our children (including mental health issues and suicidality).

Reliance on NIH Funding

8. In fiscal year 2024, my lab received funding through NIH to support one project, totaling $1.3 million. I received these funds for a grant, which runs from September 2024 to July 2027. This is an important study with critical societal benefits and the unique data collection

method we are using can be applied to different population groups, which would substantially improve our understanding of how social media is impacting the mental health of our children.

9. My lab employs three hourly workers who are funded primarily through this NIH grant, whose employment must be terminated with termination of this grant. One of these is a PhD student who work in my lab and is funded primarily through this NIH grant.

Typical Processes for NIH Grant Awards

10. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-5 year terms, though some may be longer and others may be shorter.

11. Although the life of the grant is often longer, funding is only provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the state project goals, in my experience such renewals are typically granted.

12. These regular cycles and predictable renewals are essential for the continuity of funding for my lab and my research. In my lab, we work with constantly changing technologies which require substantial amount of training, so that student workers can work on the data being collected. All this requires planning, budgeting and funding as this allows it to move it substantially forward.

13. In my experience, termination of an active grant is also extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious

scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Irregularities in Grant Terminations

14. For one of the previously approved grants for which I am principal investigator, we recently received a letter from NIH purporting to terminate the grant because it does not "effectuate agency priorities" because The letter went on to state, "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." I was not referred to any new policy statement or regulation that described the new agency priorities.

15. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that NIMH's role is to advance basic science of brain, genomics, and behavior to understand mental illnesses; chart mental illness trajectories to determine when, where, and how to intervene; highlight efforts to improve preventive and therapeutic interventions; bring knowledge to practice, improvements to services, and better outcomes to individuals. My project advances those goals by understanding how, when and why social media use impact suicidality among adolescents and youth. The study would inform parents how to protect their children from the negative impact of social media and prevent suicides. The study also has implications on timely interventions by mental health providers in preventing suicide among those adolescents and youth who are spending unhealthy amount of time on social media platforms. This is not a "research program based on gender identity" but a study on suicide prevention.

Comparisons Across Administrations

16. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

17. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

18. Due to the delays and funding uncertainty, and having sought alternative sources of funding and failed to secure them, I have been forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment;

c. Stop ongoing experiments, compromising time-sensitive components of the research. I was in the process of recruiting participants and had started data collection process, this getting stopped midway is going to impact the study

protocol. In addition, there is urgency to complete this research as it might reveal important aspects regarding social media use and how it impacts suicide;

d. Delay work on clinical translation, including potential therapeutic development such as suicide prevention intervention for adolescents who consume social media content and is mentally impacted by it.

19. Students working in my lab who are relying on research conducted there to obtain their PhDs are likely to see disruption in their progression and career development.

20. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

21. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

Priya Nambisan

Date: April 1, 2025

EXHIBIT 32

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COMMONWEALTH OF MASSACHUSETTS; et al., *laintiffs* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 1:25-cv-_____

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I, Kristian O'Connor, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Interim Vice Provost for Research and Dean of the Graduate School of the University of Wisconsin-Milwaukee. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the University of Wisconsin-Milwaukee staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

r essi nal a r nd

3. I am the Interim Vice Provost for Research and Dean of the Graduate School of the University of Wisconsin-Milwaukee, a position I have held since 2023. As Interim Vice Provost for Research and Dean of the Graduate School, I serve as UWM's Chief Research Officer and have oversight of the Office of Research, which is responsible for the administration of research activity, oversight of research policy, and compliance with federal and state

requirements. The Office of Research also provides pre- and post-award administrative support for sponsored projects. Prior to holding this position, I was the Associate Vice Provost for Research and have been a faculty member at UWM since 2002. As a faculty member, I have served as PI on several NIH awards, and in my role in the Office of Research I am currently the site PI for an inter-institutional NIH CTSA grant.

4. The University of Wisconsin-Milwaukee's statutory mission includes promoting the search for knowledge by offering research programs with emphasis on state and national needs. Wis. Stat. § 36.01(1).

5. The University of Wisconsin-Milwaukee is an R1 Research Institution with $65M total research expenditures in FY24, which includes $11.1M in funding from HHS.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts the University of Wisconsin-Milwaukee by interrupting critical health related research activities that lead to impactful research outcomes.

elian e n ndin

8. In fiscal year 2024, the University of Wisconsin-Milwaukee received funding through the National Institutes of Health ("NIH") to support dozens of projects, totaling $7.9M.

9. The University of Wisconsin-Milwaukee receives NIH grants across a variety of institutes encompassed within the NIH, including NIDA, NIGMS, NIMH, NIAAA, NIA, NIBIB, NICHHD, NINDS, and NCI.

10. Through those NIH grants, the University of Wisconsin-Milwaukee funds 20 Principal- and co-investigators.

11. The work done by the University of Wisconsin-Milwaukee on NIH funded projects provides education and training in Biomedical Engineering, Mechanical Engineering, Biology, Public Health and Health Sciences, Chemistry, Psychology, and other programs.

12. The University of Wisconsin-Milwaukee provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Wisconsin economy.

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13. The Office of Research at the University of Wisconsin-Milwaukee works with researchers to submit grant applications and tracks grant applications and awards.

14. Based on my work as Interim Vice Provost of Research and formerly Associate Vice Provost of Research I have an understanding of the NIH grant process.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at the University of Wisconsin-Milwaukee relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 9 months of submission.

20. Once a grant receives a score, the University of Wisconsin-Milwaukee is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

erminati ns rants

21. Since March 21, 2025, the University of Wisconsin-Milwaukee has had two NIH grants terminated, covering four projects. These grants funded studies on suicide prevention, as well as substance use and violence prevention.

22. The terminations received as of April 1, 2025, are attached hereto as Exhibit A.

23. These terminations will result in the loss of significant research money to the University of Wisconsin-Milwaukee.

24. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my 23 years working at the University of Wisconsin-Milwaukee, I have not seen this language previously used to cancel grants.

25. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, the University of Wisconsin-Milwaukee had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was the University of Wisconsin-Milwaukee provided with any updated "agency priorities" with which its research must align.

26. The terminated grants focus on critical issues impacting public health, including a study on suicide prevention, as well as a study on substance use and violence prevention.

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27. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

28. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

29. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

mpa t n nstit ti nal perati ns

30. Several shared research cores have seen decreased usage due to grant uncertainty, and one facility temporarily reduced staff hours due to budget delays.

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31. The terminations have disrupted ongoing research, as well as setting back the University of Wisconsin-Milwaukee for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

32. Delays have also disrupted community services, student opportunities, and public programs.

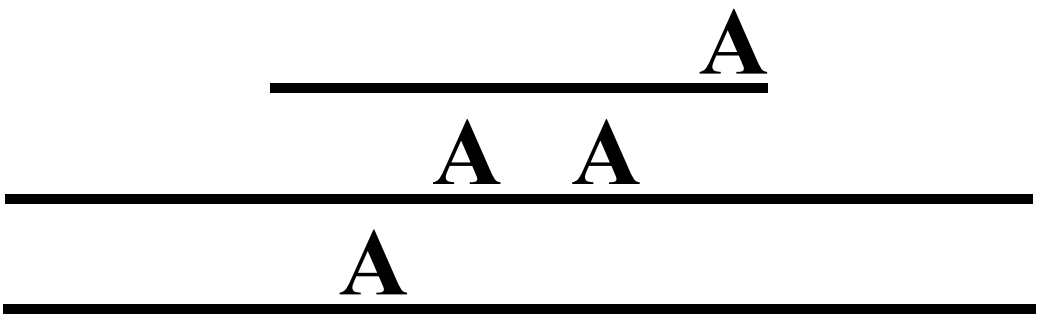
33. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

n l si n

34. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Kristian O'Connor

Date: April 2, 2025


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Tillison, Kevin <ktillison@vt.edu>
Monday, March 24, 2025 7:41 AM
Ryan C Shorey <shorey@uwm.edu>; UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Brem, Meagan <mbrem@vt.edu>
Notice of Termination: Subaward 412980-19E63 with Virginia Tech

Dear Dr. Shorey and colleagues,

Virginia Tech has received official notice of termination for grant 1R21 AA031548-01A1, entitled Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study, in accordance with 2 C.F.R. § 200.340(a)(2). As a result, we are unable to proceed with the subaward agreement. The effective date of the termination was March 20, 2025.

We appreciate your collaboration and interest in working with Virginia Tech. Please feel free to reach out if you have any questions or require further clarification.

Best Regards,

Kevin

Kevin A. Tillison, PhD
Contracts Negotiator
Virginia Tech | Office of Sponsored Programs | Federal Agency Updates
300 Turner Street NW, Suite 4200
Blacksburg, VA 24061
(540) 231-9887 | ktillison@vt.edu



Tillison, Kevin <ktillison@vt.edu>
Thursday, January 16, 2025 11:09 AM
grant-notice@uwm.edu <grant-notice@uwm.edu>
Subrecipient Signature Request: Subaward 412980-19E63 with Virginia Tech

Greeting from Virginia Tech,

Attached is the Research Subaward Agreement between Virginia Tech and the University of Wisconsin Milwaukee for the National Institute on Alcohol Abuse and Alcoholism funded research entitled: Daily Impact of Sexual Minority Stress on Alcohol-Related Intimate Partner Violence among Bisexual+ Young Adults: A Couples' Daily Diary Study.

Please review the terms and conditions and if you have any questions or concerns please let me know.

If the terms and conditions are acceptable, please have the subaward signed by an authorized official and return to my attention a partially executed agreement.

Also, prior to signature, please complete the Attachment 3B.

Thank you,

Kevin (internal reference: A5PSOEUK)

Kevin A. Tillison, PhD
Contracts Negotiator
Virginia Tech | Office of Sponsored Programs
300 Turner Street NW, Suite 4200
Blacksburg, VA 24061
(540) 231-9887 | ktillison@vt.edu





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)

Case 1:25-cv-10814-BEM Document 77-32 Filed 04/14/25 Page 13 of 13

Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Friday, March 21, 2025 11:35 AM
UWM Office of Sponsored Programs - Grant Notifications <grant-notice@uwm.edu>
Grant Termination Notification



3/21/2025

Jeremy Miner
University Of Wisconsin Milwaukee
GRANT-NOTICE@UWM.EDU

Dear Jeremy Miner:

Effective with the date of this letter, funding for Project Number 1R01MH135498-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 9/5/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6]

no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *SAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,



Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 33

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF RYAN SHOREY

I, Ryan Christopher Shorey, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am an Associate Professor at the University of Wisconsin-Milwaukee. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am an Associate Professor at the University of Wisconsin-Milwaukee. I have been a faculty member at the University of Wisconsin-Milwaukee since August 2018, where I conduct research and teach undergraduate and graduate students. Prior to that, I was a faculty member at Ohio University from Fall 2014-Spring 2018. I completed my PhD in Clinical Psychology at the University of Tennessee-Knoxville (American Psychological Association accredited; 2014).

4. I lead a laboratory focused on the impact of alcohol use on intimate partner and sexual violence among LGBTQ+ and young adult populations at the University of Wisconsin-Milwaukee. I have served as a Principal Investigator (PI) or Co-Investigator on numerous National Institutes of Health ("NIH") funded projects over the course of my career. I also currently serve as a standing member on The Social Psychology, Personality and Interpersonal Processes (SPIP) Study Section at NIH, which is a study section focused on grant applications examining the socio-personal, interpersonal, and psychological aspects of health and well-being across the lifespan.

5. I am providing this declaration to detail my experience with terminations of NIH-funded grants historically, and how that experience has changed since late January of 2025.

6. I am also providing this declaration to explain the impacts of delays in the grant review and renewal process and of grant terminations on my staff, my research, and the people who benefit from it.

7. The terminations severely impact me and my lab by completely halting critical public health research on the intersections of alcohol use and intimate partner and sexual violence; terminating the employment of a full-time project coordinator; stopping training in critical research skills for four PhD students in Clinical Psychology; halting research opportunities for undergraduate students; and causing irreparable career harm.

Reliance on NIH Funding

8. In fiscal year 2024, my lab received funding through NIH as PI and Co-PI to support five projects, totaling approximately $1,378,747. I received these funds under six grants, which run from 6 6/1/19–5/31/25; 7/22/22-3/31/27; 6/1/23–5/31/26; 8/17/23–5/31/28; 9/17/24-

8/31/26; 8/1/23-7/31/25. Critically, the dates of the awards were staggered intentionally to preserve funding for continuity of research lab operations.

9. My lab employs one worker who is funded primarily through NIH grants, whose employment I will have to terminate if my grants are terminated. I also have PhD students who work in my lab and are funded primarily through NIH, and who are relying on the work done there to complete their own research and earn their degrees. These students will lose funding and critical training opportunities if NIH funding is cutoff.

Typical Processes for NIH Grant Awards

10. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-5 year terms, though some may be longer and others may be shorter.

11. Although the life of the grant is often longer, funding is only provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the state project goals, in my experience such renewals are typically granted.

12. These regular cycles and predictable renewals are essential for the continuity of funding for my lab. Without this predictability, we are unable to hire study staff, have available supplies for studies, and unable to enroll research participants into studies as we transition from one year to the next. This severely disrupts our ability to conduct important scientific research on critical public health problems.

13. In my experience, termination of an active grant is also extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Irregularities in Grant Terminations

14. For two of the previously approved grants for which I am principal investigator, we recently received a letter from NIH purporting to terminate the grant because it does not "effectuate agency priorities." The letter went on to state, "Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs." I was not referred to any new policy statement or regulation that described the new agency priorities.

15. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that the National Institute on Alcohol Abuse and Alcoholism's role is to, in part, "Identify Patterns, Trends, and Public Health Impact of Alcohol Misuse" and "…support epidemiological research to identify and track patterns of alcohol use and misuse, drinking-related outcomes and disparities, and individual and environmental variables that confer risk or resilience." My projects advance those goals by focusing on the alcohol-related outcome of sexual assault and intimate partner violence, serious and prevalent public health problems that impacts all Americans. In our grants, we are examining the conditions under which alcohol-related sexual assault and intimate partner violence are most likely to occur, which will have significant implications for addressing these costly public health problems. In addition, our grants focus on

both individual and environmental variables that confer risk and resilience for alcohol use and adverse alcohol-related outcomes. We are examining the impact of various daily and distal stressors on risk for alcohol use, how sexual assault and intimate partner violence impact subsequent alcohol use, and how social support may act as a resilience factor for alcohol use and the adverse impacts of alcohol use. This is not a "research program based on gender identity" but a study on substance use and violence prevention.

Comparisons Across Administrations

16. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses and awards. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

17. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

18. Due to the delays and funding uncertainty, and having sought alternative sources of funding and failed to secure them, I have been forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment;

c. Stop ongoing research, compromising time-sensitive components of the research. For example, I have had to stop two longitudinal studies, pausing the research participation of dozens of people who consented to engage in this research. This will result in significant disruptions to the overall quality of the science and difficulty translating this critical work to into effective public health initiatives designed to improve the lives of Americans.

19. Students working in my lab who are relying on research conducted there to obtain their PhDs are likely to see disruptions in their progression and career development.

20. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

21. The breakdown in NIH processes is affecting my lab, my staff, my research, and those individuals who stand to benefit from my research. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

_____

Ryan C. Shorey

Date: April 1, 2025

EXHIBIT 34

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF PETER G. BARR-GILLESPIE

I, Peter G. Barr-Gillespie, Ph.D, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Executive Vice President and Chief Research Officer of Oregon Health & Science University ("OHSU"). In addition, I am a Professor with the OHSU Oregon Hearing Research Center and an affiliated scientist with the Vollum Institute. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the OHSU staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Executive Vice President and Chief Research Officer at OHSU, having held that position or an equivalent one for seven and a half years. I am also a Professor in the Department of Otolaryngology, and I have been running a research lab at OHSU since 1999. Prior to that I was an Assistant, then Associate Professor in the Department of Physiology at

Johns Hopkins University, where I was from 1993-1999. I received my postdoctoral training in neuroscience from Dr. James Hudspeth at the University of California San Francisco from 1988-1989 and at the University of Texas Southwestern Medical Center from 1989-1993. I earned a BA in chemistry from Reed College in 1981 and a PhD in pharmacology from the University of Washington in 1988.

4. OHSU's statutory mission is to provide healthcare, education and conduct research that supports the people of the State of Oregon.

5. OHSU houses a robust research program with approximately 1,415 faculty investigators and 262 postdoctoral scholars.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts OHSU by cutting off funding to research faculty members, preventing their ability to continue to support their own salaries and those of the research staff in their labs. This funding shortfall will both lead to faculty layoffs and negatively impact OHSU's budget to support research.

Reliance on NIH Funding

8. In fiscal year 2024, OHSU received funding through the National Institutes of Health ("NIH") to support 784 projects, totaling $353.33 million.

9. OHSU receives NIH grants across a variety of institutes encompassed within the NIH, including National Institute of Allergy & Infectious Diseases, National Institute on Aging, National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Child Health and Human Development, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute of Neurological Disorders and Stroke, National Eye Institute, National Institute of General Medical Science, National Human Genome Research Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Mental Health, National Institute on Deafness and Other Communication Disorders, and the National Institute of Dental and Craniofacial Research, amongst others.

10. Through those NIH grants, OHSU funds approximately 1,415 researchers.

11. The work done by OHSU on NIH funded projects provides education and training in PhD-granting graduate programs in Behavioral Neuroscience, Biomedical Engineering, Biomedical Sciences, Clinical Psychology, and Neuroscience.

12. OHSU provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the OREGON economy.

13. As an example of impact on OHSU infrastructure, we have submitted a C06 construction grant to the NIH to support construction of a Biosafety Level 3 (BSL-3) laboratory, but that project is on hold while the grant review has been postponed.

Typical Timeline and Processes for NIH Grant Awards

14. The Office of Proposal & Award Management at OHSU works with researchers to submit grant applications and tracks grant applications and awards.

15. Based on my work as Professor and Chief Research Officer, I have an understanding of the NIH grant process based on my 25 years in those roles.

16. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

17. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

18. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

19. The process for competitive renewals is very similar, but it is even more likely for a grant that has been funded in the past to be renewed.

20. The budget process at OHSU relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within six months of submission.

21. Once a grant receives a score, OHSU is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

22. Since late January 2025, OHSU has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

23. OHSU has not received formal notice of changes for many of these grants. For others, OHSU has gotten only a notification that proposals are "paused" or "under review."

24. As of March 31, 2025, OHSU has approximately 280 proposals totaling $731.6 million awaiting NIH study section review.

25. As of March 31, 2025, OHSU has 70 proposals totaling $172.4 million that received fundable scores, awaiting NIH advisory council and Notice of Award.

26. As of March 31, 2025, OHSU has 90 proposals totaling $194.9 million that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

27. Since March 24, 2025, OHSU has received a notice of termination of one NIH grant awarded directly to OHSU, as well as seven subawards issued from other institutions which had their NIH award terminated. We have received multiple notifications from NIH that additional terminations are imminent.

28. The notice of termination received as of March 24, 2025 is attached hereto as Exhibit A. The overall goal of this project is to utilize the nonhuman primate model to identify the mechanisms responsible for the metabolic disorders associated with long COVID. The termination states, "The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

29. The notice of termination for one of the subawards involved an antiviral drug discovery project.

30. These terminations will result in the loss of $2.4 million in research money to OHSU.

31. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my 25 years working at OHSU, I have not seen this language previously used to cancel grants.

32. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, OHSU had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was OHSU provided with any updated "agency priorities" with which its research must align.

Comparisons Across Administrations

33. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

34. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo and renewals have been delayed.

35. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations.

36. These delays have forced us to implement bridge funding for dozens of faculty, drawing from limited discretionary resources. As of April 1, 2025, OHSU has implemented bridge funding of approximately $1 million during the FY25 fiscal year. This prevents the use of these funds for any other purpose, including other planned improvements to our programs and research.

37. We have paused start-up funding for new hires whose research programs depend on timely NIH awards. This includes several new hires we had provided offer letters to and for whom OHSU had taken steps to prepare for their arrival.

Admissions, Training and Workforce Disruptions

38. OHSU uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

39. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

40. We have international postdocs whose visa status is now at risk due to pending NIH awards that were expected to renew this spring.

41. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the

research capabilities of OHSU, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

42. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

43. Several proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

44. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

45. The delays have disrupted ongoing research, as well as setting back OHSU for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel. This is in spite of the interim funding measures being taken by OHSU to keep certain research going. OHSU has had to consider which of these valuable programs to continue with these limited funds.

46. Some of these studies involve the use of animal test subjects, all of which would need to be euthanized due to loss of funding.

47. Some of these studies had the potential to achieve breakthroughs in many different disciplines, which would have advanced public health, and which will now not occur.

48. Delays have also disrupted community services, student opportunities, and public programs.

49. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

50. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Signed by:
Peter Barr-Gillespie
455E7C4804C8478...

Peter G. Barr-Gillespie, Ph.D,

Date: 4/3/2025

EXHIBIT A

Kellie Guentert

Subject: FW: Grant Termination Notification
Attachments: 1015566-002_Roberts_3R01DK122843-05S1-APRC01318_50224 (2).pdf

Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Monday, March 24, 2025 12:52 PM
Jason Jaworski <jaworski@ohsu.edu>
[EXTERNAL] Grant Termination Notification





3/24/2025

Jaworski, Jason N
Oregon Health & Science University
jaworski@ohsu.edu

Dear Jaworski, Jason N:

Effective with the date of this letter, funding for Project Number 3R01DK122843-05S1 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 7/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

The end of the pandemic provides cause to terminate COVID-related grant funds. These grant funds were issued for a limited purpose: to ameliorate the effects of the pandemic. Now that the pandemic is over, the grant funds are no longer necessary.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Dee Doherty, Chief Grants Management Officer, NIDDK
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] NIH Grants Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT 35

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF SUSAN PHILIP

I, Susan Philip, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the following information is true and correct:

1. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the San Francisco Department of Public Health (SFDPH) staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am physician board certified in both Internal Medicine and Infectious Diseases, the Health Officer for the City and County of San Francisco (the City), and the Director of the Population Health Division (PHD) of the SFDPH. SFDPH is a City department whose mission is to protect and promote the health of all San Franciscans.

4. I received my M.D. from Washington University in St. Louis and trained as a resident in Internal Medicine at the University of Chicago. I also have an MPH from the Harvard

School of Public Health, after which I completed a fellowship in Infectious Diseases at the University of California, San Francisco (UCSF). I am an Assistant Clinical Professor of Medicine in the Division of Infectious Diseases at UCSF, and have previously been an HIV primary care provider at San Francisco City Clinic

5. As the City's Health Officer, I am charged under California law with taking any preventative measure that may be necessary to protect and preserve the public health from any public health hazard during a 'state of war emergency,' 'state of emergency,' or 'local emergency.' I am also responsible for issuing orders to other governmental entities within my jurisdiction to take any action that I deem necessary to control the spread of the communicable disease.

6. As Director of PHD, I oversee 16 branches within SFDPH that promote and protect public health through mandated public health functions including disease surveillance, environmental safety, health promotion and chronic disease prevention, preparation and response to public health emergencies, and monitoring of emerging and ongoing infections and diseases.

7. In addition, I closely supervise and monitor the Research, Learning, and Development Group, which is comprised of three branches: Bridge HIV, Center for Public Health Research (CPHR), and Center for Learning and Innovation. Bridge HIV and CPHR are the only two research branches of SFDPH, where experts conduct nationally and internationally recognized research in multiple public health fields, including HIV and substance use.

8. SFDPH's research program has been conducting cutting-edge research focused on the practical population health needs of its communities for over 30 years. It is very unusual to have a county public health program that performs its own research, let alone a program that consistently wins prestigious competitive grants from the National Institutes of Health (NIH).

San Francisco's discoveries provide benefits nationwide. For example, SFDPH clinics were the first to recommend doxycycline post-exposure prophylaxis (doxyPEP) to reduce transmission of STIs. The City has seen population-level decreases in syphilis and chlamydia infections and planned further research to refine and study doxyPEP treatment.

9. I am providing this declaration to explain the impacts of delay and/or cancellation of City grants by the NIH.

Typical Timeline and Processes for NIH Grant Awards

10. Researchers from Bridge HIV and the Center for Public Health Research submit grant applications and track applications and awards as part of the Population Health Division.

11. Based on my 20 years of work at SFDPH, I have an understanding of the NIH grant process.

12. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

13. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some ICs publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to

balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding

14. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to recommend a grant for funding is made. After the advisory council meets, the relevant institute's Director typically approves the recommended grants, and a Notice of Award is promptly issued confirming the grant will be funded.

15. The process for competitive renewals is very similar, except that a grant that has been funded in the past is even more likely to be renewed.

16. The budget process at SFDPH relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within months of submission.

17. Once a grant receives a score, SFDPH is able to consider whether to include the funding coming from that grant as part of its budget for the coming year

Delays and Irregularities in the Processing of NIH Grant Applications

18. Since late January 2025, the City has seen an unusual number of delays in the processing of NIH grant applications. PHD is the subrecipient of incoming grants that have been significantly delayed. PHD anticipated receiving a Notice of Award (NOA) for the following grants: the Bridge Clinic: Optimizing Injectable PrEP Delivery for Transgender and Non-Binary People; Project Chill: Randomized controlled trial of as-needed olanzapine for self-management of methamphetamine-associated psychosis; the Camino Study: Evaluating a pilot legal intervention to reduce HIV risk among high risk Latina/o/x sexual/gender minorities; and the BEYOND Study.

19. PHD had previously been informed that it would receive these funds as long PHD had "satisfactory programmatic progress" and there was an "availability of funds." On information and belief, I understand these conditions have been met for each of the above-mentioned grants.

20. PHD has not received formal notice of changes for these grants, and has only been advised that the proposals are "paused" or "under review."

21. As of April 2, 2025, PHD is awaiting roughly $3 million in grants from NIH.

Terminations of NIH Grants

22. Since late January 2025, NIH has terminated twelve grants that funded PHD research.

23. The notices of termination received as of April 2, 2025 are attached hereto as Exhibits A-I.

24. These terminations will result in the loss of roughly $1,204,788.00 in research money to SFDPH.

25. The termination notices for these grants have provided very little explanation as to the reason for the terminations, noting only that the research no longer "effectuates agency priorities." In my 20 years of working at SFDPH, I have not seen this language previously used to cancel grants.

26. The termination notices also state that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, SFDPH had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was SFDPH provided with any updated "agency priorities" with which its research must align.

27. The terminated grants include the following: Tailoring Delivery of LongActing PrEP for Cisgender MSM who use methamphetamine; MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women; PrEP-3D: An Integrated Pharmacy Digital Diary and Delivery Strategy to Increase PrEP Use Among MSM; SHINE: Strong: Building The pipeline of HIV behavioral scientists with expertise in trans pop health; One Ballroom: Understanding Intersectional Stigma to Optimize the HIV Prevention Continuum among Vulnerable Populations in the United States; T'Cher, Take Charge: PrEP for trans women in the Deep South; DoxyPEP Impact Study; Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) HIV and Pregnancy Prevention in Youth (HAPPY); ATN Operations and Collaborations Center; ATN Scientific Leadership Center; Short Trainings on Methods for Recruiting, Sampling, and Counting Hard-to-Reach Populations: The H2R Training Program.

Comparisons Across Administrations

28. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

29. Renewals were routine and predictable. Terminations were exceedingly rare and followed due process.

30. This year, even long-standing, high-performing programs are in limbo. The current approach is without precedent in our experience.

Concerns About FY25 Funds Being Obligated

31. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

32. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

33. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

34. The City and County of San Francisco is severely harmed by NIH's funding delays and terminations. The City's capacity to create research-informed public health programs is diminished; one-half of the City's public health research projects has been terminated or delayed by NIH. For example, all of SFDPH's research comes from Bridge HIV and the Center for Public Health Research at SFDPH. Over fifty percent of Bridge HIV's research projects have been terminated by NIH. And the Center for Public Health Research had 12 ongoing research projects, but only 4 have not been impacted by the NIH's terminations, delays, and failure to review and renew grants.

35. SFDPH's grants are aimed at stopping the spread of communicable diseases including HIV. NIH terminated almost the entirety of SFDPH's research into PrEP, a medication that significantly reduces a person's risk of contracting HIV. SFDPH's PrEP research is meant to support San Francisco "Getting to Zero San Francisco" initiative, which aims to achieve zero new HIV infections, zero HIV-related deaths, and zero HIV stigma by 2025.

36. NIH terminated or delayed SFDPH research intended to engage with vulnerable populations who have a higher rate of contracting and spreading communicable diseases, such as

the transgender community and drug users. Over $800,000 has been lost towards this goal, further impacting the City's ability to reach its "Getting to Zero San Francisco" goal.

37. NIH's terminations and delays have also impacted SFDPH's ability to maintain its workforce. SFDPH will lose vital researchers, analysts, and staff if it cannot replace the funding NIH terminated. SFDPH has also had to terminate recruitment efforts due to lack of funding.

38. NIH's terminations and delays have also impacted SFDPH's capacity to prevent the spread of other communicable diseases, including bacterial STIs. Specifically, NIH terminated funding for the Doxy-PEP Impact Study (DoxyImpact), a longitudinal study to assess the use of post-exposure doxycycline in preventing bacterial STI transmission at study sites in five U.S. cities.

39. In many cases, there is no way to recover the lost time, research continuity, or training value once the research is disrupted.

40. The delays have disrupted ongoing research, and will inhibit SFDPH's capacity to conduct research going forward. Funding gaps have forced researchers to abandon studies or lose key personnel.

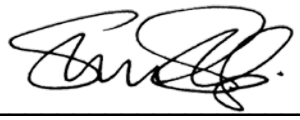
Conclusion

41. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

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I declare under penalty of perjury under the laws of the United States that, to the best of my knowledge, the foregoing is true and correct.

Executed on April 2, 2025, at San Francisco, California



Susan Philip, MD, MPH

EXHIBIT A

FDP Subaward Amendment

Awarding Agency: National Institutes of Health (NIH)
Amendment No: 1
PTE/Prime Award No.: 7R21DA058575-02
Subaward No: AH1058/PH1058A CCSF DPH

Pass-Through Entity (PTE)		Subrecipient
Harvard Pilgrim Health Care, Inc., on behalf of itself and Harvard Pilgrim Health Care Institute, LLC	Entity Name	City and County of San Francisco Department of Public Health
research_admin@hphci.harvard.edu	Contact Email	albert.liu@sfdph.org
Vanessa McMahan, PhD	Principal Investigator	Albert Liu

Project Title: Tailoring Delivery of LongActing PrEP for Cisgender (MSM) Who Use Methamphetamine

Cumulative Budget Period(s) (Agreement Start Date) Start Date: 09/01/2024 (End Date of Latest Budget Period) End Date: 03/21/2025	Amount Funded This Action	Total Amount of Funds Obligated to Date
	$ 0.00	$ 23,393.00

Subrecipient Cost Share ☐ | Subject to FFATA ■ | Subrecipient UEI (Unique Entity Identifier - May leave blank if unchanged from prior Agreement): DCTNHRGU1K75

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Subaward Agreement as follows:

☐ **Additional Budget Period**

☐ **No Cost Extension**

☐ **Additional Funding**

☐ **Deobligation**

Carryover is

☐ **Carryover Authorized**

☐ **Detailed Budget/Scope of Work/Notice of Award Attached** (Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")

■ **Other (See Below)**

Notice of early termination effective 03/21/2025

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Date		Date	
Name	Cary Williams	Name	
Title	Director, Office of Sponsored Programs	Title	

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON DRUG ABUSE

Notice of Award
FAIN# R21DA058575
Federal Award Date
03/21/2025

Recipient Information

1. Recipient Name
HARVARD PILGRIM HEALTH CARE INC
1 WELLNESS WAY
CANTON, MA 02021

2. Congressional District of Recipient
08

3. Payment System Identifier (ID)
1042452600A1

4. Employer Identification Number (EIN)
042452600

5. Data Universal Numbering System (DUNS)
071721088

6. Recipient's Unique Entity Identifier
NZVVQ8GNVX65

7. Project Director or Principal Investigator
Vanessa McMahan

vanessa_mcmahan@hphci.harvard.edu
617-864-4260

8. Authorized Official
Cary Williams
research.admin@hphci.harvard.edu
617-867-4958

Federal Agency Information

9. Awarding Agency Contact Information
Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE
pfleming@mail.nih.gov
301-480-1159

10. Program Official Contact Information
Richard A Jenkins
Health Scientist Administrator
NATIONAL INSTITUTE ON DRUG ABUSE
jenkinsri@mail.nih.gov
301-443-6504

Federal Award Information

11. Award Number
7R21DA058575-02

12. Unique Federal Award Identification Number (FAIN)
R21DA058575

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Tailoring Delivery of LongActing PrEP for Cisgender (MSM) who Use Methamphetamine

15. Assistance Listing Number
93.279

16. Assistance Listing Program Title
Drug Abuse and Addiction Research Programs

17. Award Action Type
Change of Recipient Organization (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$220,370
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$220,370
26. Project Period Start Date 09/01/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$220,370

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Pamela G. Fleming

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON DRUG ABUSE

SECTION I – AWARD DATA – 7R21DA058575-02 REVISED

Principal Investigator(s):
Vanessa McMahan

Award e-mailed to: research_admin@hphci.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Drug Abuse of the National Institutes of Health under Award Number R21DA058575. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Pamela G. Fleming
Grants Management Officer
NATIONAL INSTITUTE ON DRUG ABUSE

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$28,998

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Fringe Benefits	$8,641
Personnel Costs (Subtotal)	$37,639
Travel	$4,000
Subawards/Consortium/Contractual Costs	$99,331
Publication Costs	$3,000
Federal Direct Costs	$143,970
Federal F&A Costs	$76,400
Approved Budget	$220,370
Total Amount of Federal Funds Authorized (Federal Share)	$220,370
TOTAL FEDERAL AWARD AMOUNT	$220,370
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$220,370	$220,370

Fiscal Information:
Payment System Identifier: 1042452600A1
Document Number: RDA058575B
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
DA	8472628	$220,370

NIH Administrative Data:
PCC: CV/RJP / **OC**: 41025 / **Released**: 03/21/2025
Award Processed: 03/22/2025 12:10:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 7R21DA058575-02 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 7R21DA058575-02 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than

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the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21DA058575. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – DA SPECIFIC AWARD CONDITIONS – 7R21DA058575-02 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION #1 - TERMINATION

It is the policy of NIH not to further prioritize research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination since race and other protected characteristics, which harms the health of Americans.
Therefore, this project is terminated.

The Harvard Pilgrim Health Care, Inc. may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered.

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Please be advised that your organization, as part of the orderly closeout process, will need to submit the necessary closeout documents (i.e. Final Research Performance Program Report (F-RPPR), Final Invention Statement (FIS), and the Final Federal Financial Report (FFR)) within 120 days of the end date of this grant to avoid unilateral closeout.

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

This revision supersedes Notice of Award (NoA) issued 8/09/2024.

_____

CHANGE OF RECIPIENT
Support for this project was previously funded via 1 R21 DA 058575-01 at Public Health Foundation Enterprises.

CONSORTIUM ACTIVITY
This award includes funds awarded for consortium activities. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS), Section on Consortium Agreements - http://grants.nih.gov/policy/nihgps/index.htm.

The recipient is reminded of the *NIH Final Updated Policy Guidance for Subaward/Consortium Written Agreements* as published in the NIH Guide notice NOT-OD-23-182 on September 15, 2023 with an effective date of January 1, 2024. The notice can be found here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-182.html

NOFO REQUIREMENTS
This award is subject to the requirements detailed in PAR-22-109, “Dissemination and Implementation Research in Health (R21 Clinical Trial Optional): posted on 05/10/2022 which are incorporated by reference as terms and conditions of this award.

The NOFO is available here: PAR-22-109: Dissemination and Implementation Research in Health (R21 Clinical Trial Optional) (nih.gov)

NIDA TERMS
In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm), in order to most effectively disseminate research results, advance notice should be given to NIDA that research findings are about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the NIDA Special Considerations Page for guidance on coordination with the NIDA Press Office at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding, or contact the NIDA Press Office at media@nida.nih.gov.

Please see Special Considerations for NIDA Funding Opportunities and Awards at https://www.drugabuse.gov/funding/special-considerations-for-nida-funding.

SPREADSHEET SUMMARY
AWARD NUMBER: 7R21DA058575-02 REVISED

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INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget	Year 2
Salaries and Wages	$28,998
Fringe Benefits	$8,641
Personnel Costs (Subtotal)	$37,639
Travel	$4,000
Subawards/Consortium/Contractual Costs	$99,331
Publication Costs	$3,000
TOTAL FEDERAL DC	$143,970
TOTAL FEDERAL F&A	$76,400
TOTAL COST	$220,370

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	66%
F&A Cost Base 1	$115,757
F&A Costs 1	$76,400

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EXHIBIT B

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

March 26, 2025

San Francisco Department of Public Health
101 Grove Street, Room 410
San Francisco, CA 94102
Attention: Sajid Shaikh
Phone: (415) 554-2778
Email: Sajid.shaikh@sfdph.org

Subject: NIH Termination Letter: Notification of Termination

We are writing to formally notify you that Heluna Health received a termination letter from the National institutes of Health (NIH) for Project Number 1R34MH132405-01 (HH Project Number: 1067.0101) to cease all activities associated with this project effective March 21, 2025.

Costs resulting from financial obligations incurred after termination are not allowable. To comply with this termination, Heluna Health is initiating the closeout requirements for this project.

To facilitate the closeout process, as listed in your attached Amendment #1 please submit your final invoice for cost incurred no later than March 21, 2025, along with required back up documentation as stated in the attached Amendment #1, by April 11, 2025.

Amendment #1 is attached. Please return the signed amendment no later than March 31, 2025.

If you have any questions, please contact Adam Abate, Senior Contract and Grant Manager, at AAbate@HelunaHealth.org

Sincerely,

DocuSigned by:
Rochelle McLaurin
11FA7C5B062940D...

Rochelle McLaurin
Director, Contracts and Grants Management

Attachment:

Amendment Number 1:

CC:

Susan Buchbinder

Peter Dale

Rochelle McLaurin

Adam Abate

Docusign Envelope ID: 878C1F25-FF3E-40BB-90B5-AGC2E062A96E

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969
13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
Phone: 800.201.7320 | Fax: 562.205.2453 | www.helunahealth.org

SUBCONTRACT/SUBRECIPIENT AMENDMENT 1

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

1067.0101 MYPREP PLUS

This [Subcontract/Subaward] Agreement (this "Agreement") is amended as follows:

Pursuant to Section 6 Term and Termination, Clause C Termination for cause, Part 2 of the Agreement, "if either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services," effective March 21, 2025, funding for Project Number 1R34MH132405-01 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grant Policy Statement, and 2 C.F.R. § 200.340 (a)(2). Heluna Health along with City and County of San Francisco will be terminating the Subcontract for the project titled "MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women". City and County of San Francisco should cease services as of the effective date of termination March 21, 2025, and cancel any outstanding obligations and not incur any additional obligations.

TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from September 7, 2023, and is amended to end on March 21, 2025.

EXHIBIT D – FORM OF INVOICE

The final invoice is due April 11, 2025 via email to Tyler Norgord at TNorgord@helunahealth.org with a copy to Adam Abate AAbate@helunahealth.org.

All other terms and conditions of the original Subcontract/Subaward Agreement remain in full force and effect.

Signatures acknowledging this amendment are below.

HELUNA HEALTH

By: DocuSigned by: Rochelle McLaurin 11FA7C5B062940D... _____ Date: 3/26/2025

Rochelle McLaurin
Director, Contract and Grant Management

THE CITY AND COUNTY OF SAN FRANCISCO

By: _____ Date: _____

Grant Colfax, MD
Director of Health
Department of Public Health

Approved as to Form

David Chiu
City Attorney

By: _____ Date: _____

Henry Lifton
Deputy City Attorney

Docusign Envelope ID: 878C1F25-FF3E-40BB-90B5-AGC2E062A96E

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

13300 Crossroads Parkway North, Suite 450 | City of Industry, CA | 91746
Phone: 800.201.7320 | Fax: 562.205.2453 | www.helunahealth.org

[SUBCONTRACT/SUBAWARD] AGREEMENT BETWEEN

HELUNA HEALTH

AND

CITY AND COUNTY OF SAN FRANCISCO

This [Subcontract/Subaward] Agreement (this "Agreement") is made and entered into as of 4/19/2024 by and between PUBLIC HEALTH FOUNDATION ENTERPRISES, INC., DBA Heluna Health, a 501(c)(3) California nonprofit corporation (hereinafter referred to as "HELUNA HEALTH"), and the party identified in Section 1 below (hereinafter be referred to as "Subcontractor/Subawardee."

RECITALS

A. HELUNA HEALTH has been granted an award by Department of Health and Human Services (the "Funding Agency"); under contract number 1R34MH132405-01; Federal Award Identification Number (FAIN) R34MH132405; and Catalog of Federal Domestic Assistance (CFDA) number 93.242 under which HELUNA HEALTH and its subcontractors and subawardees will collaborate on the program.

B. Subcontractor/Subawardee has expertise in the necessary area(s) which their expertise can assist HELUNA HEALTH to perform its obligations under the Funding Award Agreement; and

C. HELUNA HEALTH desires to engage the services of Subcontractor/Subawardee to assist HELUNA HEALTH in the performance of certain of its obligations under the Funding Award Agreement as set forth herein.

D. The Parties understand and agree that any funding amount above $1,000,000, that constitutes revenue to the City requires formal approval by the San Francisco Board of Supervisors acting in its sole discretion under San Francisco Charter Section 9.118.

AGREEMENT

1. IDENTITIES OF PARTIES

SUBCONTRACTOR/SUBAWARDEE:

Legal Name of Subcontractor/Subawardee: City and County of San Francisco
DBA of Subcontractor/Subawardee: San Francisco Department of Public Health
Type of Entity: [ ] Sole Proprietorship; [ ] Partnership; [ ] Corporation;
[ ] Limited Liability Company; [X] Government

State of Organization (if an entity): California
Address: 101 Grove Street, Room 402
City/State/Zip: San Francisco, CA 94102
Business Telephone: (415) 554-2778
Social Security or Employer Identification Number: 94-6000417
License Number and Expiration Date, if any: N/A
Email Address: Sajid.shaikh@sfdph.org

Name of Principal Investigator/Project Coordinator: Susan Buchbinder
Phone Number of Principal Investigator/Project Coordinator: (415) 476-2300

Is Subcontractor/Subawardee required to file a Single Audit with the Federal Government? (Required for parties who receive Federal funds in the aggregate amount of $750,000 or more):
[X] Yes [ ] No

If yes, has Subcontractor/Subawardee filed the required Single Audit? [X] Yes [ ] No
(If yes, submit copy to HELUNA HEALTH prior to signing this Agreement)

HELUNA HEALTH:

Heluna Health
Address and Phone #: 13300 Crossroads Parkway North, Suite 450, City of Industry, CA, 91746-3505; (562) 699-7320
Program Name: MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women
Program/CID #: 1067.0101
Project Director Name: Susan Buchbinder
Project Director Phone #: (415) 476-2300
Project Director Email Address: susan.buchbinder@sfdph.org
Contracts Manager Name: Adam Abate
Contracts Manager Email Address: AAbate@helunahealth.org

2. SCOPE OF SERVICES

(a) Services. Subcontractor/Subawardee shall perform the services, duties and obligations set forth in the Statement of Work ("SOW") attached as Exhibit A hereto, which is made a part hereof and incorporated herein by reference (the "Services"). The Services relate Exhibit C, if attached hereto. Subcontractor/Subawardee shall perform the Services in accordance with the specifications, timetables and requirements set forth in the SOW and this Agreement. HELUNA HEALTH may, in its discretion, provide to Subcontractor/Subawardee a copy of the Funding Award Agreement or the relevant sections thereof. If Subcontractor/Subawardee is provided with a copy of the Funding Award Agreement or the relevant sections thereof, Subcontractor/Subawardee shall carefully review them and shall

perform the Services in accordance with the specifications, timetables and requirements set forth therein.

(b) Location(s) of Services. Subcontractor/Subawardee shall perform the Services at the following location(s):

101 Grove Street, Room 402
San Francisco, CA 94102

(c) Subcontractor/Subawardee Principal Investigator/Project Coordinator. Subcontractor/Subawardee shall appoint the Principal Investigator/Project Coordinator (the "PI") identified above to be primary point of contact with HELUNA HEALTH with respect to the Services and to have primary responsibility within Subcontractor's/Subawardee's organization for the performance of the (technical or programmatic) aspects of the Services. Subcontractor/Subawardee shall not replace or reassign the PI without HELUNA HEALTH's prior written approval.

(d) HELUNA HEALTH Project Director. The HELUNA HEALTH Project Director identified above shall be primarily responsible on behalf of HELUNA HEALTH for the overall direction of the Services, including review and approval of Subcontractor's/Subawardee's performance of the Services. HELUNA HEALTH will notify Subcontractor/Subawardee if HELUNA HEALTH replaces or reassigns such Project Director.

(e) Performance Reporting. If requested by HELUNA HEALTH or the Funding Agency, Subcontractor/Subawardee shall submit a final technical or performance report, annual performance report, and quarterly performance reports. The final report shall be due 30 days after expiration or termination of this Agreement; annual reports and quarterly reports shall be due 30 days after the reporting period. Subcontractor/Subawardee shall also provide any other reports as may be requested by HELUNA HEALTH. Performance reports shall include a comparison of actual accomplishments with goals and objectives established for the period, findings of the PI, or both, as requested by HELUNA HEALTH. Where possible, quantitative output data should be related to cost data for computation of unit costs. Other pertinent information will include, when appropriate, the reasons why established goals were not met and an analysis. Subcontractor/Subawardee shall immediately notify HELUNA HEALTH of developments that have a significant impact on the performance of the Services hereunder and of any problems, delays, or adverse conditions that materially impair its ability to meet the objectives of the Services, including providing a statement of the action taken or contemplated and any assistance needed to resolve the situation.

3. COMPLIANCE WITH FUNDINGAWARD AGREEMENT AND LAWS AND REGULATIONS; FLOW DOWN PROVISIONS

(a) Compliance with Funding Contract. Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of

the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached hereto as Exhibit C, that are applicable to Subcontractor/Subawardee and Subcontractor's/Subawardee's activities.

(b) Flow Down Provisions. Without limiting the generality of Section 3(a) above, Subcontractor/Subawardee shall comply with, and shall ensure that all of its personnel and lower-tier subcontractors comply with, all of the flow-down provisions of the Funding Award Agreement applicable to Subcontractor/Subawardee, if attached as Exhibit C (the "Flow Down Provisions"). Subcontractor/Subawardee represents and warrants that it has carefully reviewed all of the Flow Down Provisions, if attached as Exhibit C, and is able to comply with all of the Flow Down Provisions. In the event that the requirements set forth in the Flow Down Provisions are greater than the requirements set forth in this Agreement, or in the event of any conflict between the provisions of this Agreement and the Flow Down Provisions, the Flow Down Provisions shall control and Subcontractor/Subawardee shall comply with the requirements set forth in the Flow Down Provisions in accordance with Section 2(a).

(c) Laws and Regulations. Subcontractor/Subawardee shall also comply with all state and federal statutes and regulations applicable to Subcontractor/Subawardee, the Services or the Funding Award Agreement, in performing its obligations under this Agreement. Without limiting the generality of the foregoing, Subcontractor shall:

(i) unless exempt, comply with the requirements under 45 CFR Part 74, and the Public Health Service Grants Policy Statement;

(ii) unless exempt, comply with Executive Order 11246 entitled "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemental in Dept. of Labor regulations (41 CFR Part 60);

(iii) comply with (and not violate) all statutes, laws, rules and regulations relating to non- discrimination against any employees or applicants for employment, including, without limitation, Title VII of the Civil Rights Act of 1964, The Americans with Disabilities Act Amendments Act of 2008, and the California Fair Employment and Housing Act (if Subcontractor/Subawardee is located within California), and shall take affirmative action to ensure that all employment related decisions are made in conformance with all such statutes, laws, rules and regulations; and

(iv) unless it is exempt from doing so, comply with 45 CFR Part 76, Appendix B-Certification Regarding Debarment, Suspension, and Ineligibility, Voluntary Exclusion-Lower Tier Covered Transactions.

(d) HIPAA Business Associate Agreement. If the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") is applicable to the Services, Subcontractor/Subawardee shall execute and deliver HELUNA HEALTH's standard Business Associate Agreement as required by HIPAA.

(e) Lower-tier Subcontractors/Subawardees. Subcontractor/Subawardee shall incorporate all of the terms and conditions of this Agreement into all lower-tier subcontracts that Subcontractor/Subawardee may enter into in connection with this Agreement, and shall ensure that all such lower-tier subcontractors/subawardees and their personnel comply with all of the requirements of this Agreement applicable to Subcontractor/Subawardee, and all of the rules, requirements and restrictions set forth in the Funding Award Agreement, if attached as Exhibit C, including the Flow Down Provisions, that are applicable to such lower-tier subcontractors'/subawardees' activities.

4. PAYMENT FOR SERVICES

(a) Budget. The total compensation and reimbursements payable to Subcontractor/Subawardee hereunder shall be as set forth in the detailed budget for the Services attached hereto as Exhibit B (the "Budget"), which is made a part hereof and incorporated herein by reference. The maximum amount payable to Subcontractor/Subawardee hereunder shall not exceed the maximum amount set forth in the Budget.

(b) Must Stay Within Budget Time Periods. Subcontractor/Subawardee shall be compensated only for Services actually performed by Subcontractor/Subawardee and within the appropriate time period set forth in the Budget.

(c) Approval of Services by HELUNA HEALTH. All Services must be completed to the satisfaction of HELUNA HEALTH in order to be entitled to payment hereunder.

(d) Funds Available to HELUNA HEALTH. HELUNA HEALTH shall not be obligated to make payment under this Agreement unless the corresponding funds are disbursed to HELUNA HEALTH under the Funding Award Agreement.

(e) Billing of Expenses and Costs. All expenses and costs shall be billed in accordance with the approved budget. Expenses incurred after the expiration or termination of this Agreement shall be disallowed. Subcontractor/Subawardee shall submit its final invoice no later than 30 days after the date of expiration of the term or termination of this Agreement.

(f) Budget Modifications. The Budget may be modified only by written agreement of HELUNA HEALTH and Subcontractor/Subawardee and the prior written approval of the Funding Agency.

5. INVOICING PROCEDURES

(a) Approval by Funding Agency. If required under the Funding Award Agreement, attached hereto as Exhibit C, Subcontractor/Subawardee must first submit all timesheets and invoices to the Funding Agency for approval by the Funding Agency. After the Funding Agency

has approved a timesheet and invoice submitted by Subcontractor/Subawardee, Subcontractor/Subawardee shall submit the same to HELUNA HEALTH.

(b) Address for Invoices. Subcontractor/Subawardee shall send all timesheets and invoices to the attention of the HELUNA HEALTH Project Director at the address set forth in Section 1 above.

(c) Invoicing Period. All invoices shall be submitted not more frequently than monthly, in arrears and must be submitted to HELUNA HEALTH within 30 days after the end of the applicable month or within 15 days after approval by the Funding Agency (if applicable), whichever is later. All final invoices must be received within 30 days of the expiration or termination of this Agreement or within such earlier time period as HELUNA HEALTH may require. If any invoices are not submitted within such time periods, Subcontractor/Subawardee waives (in HELUNA HEALTH's discretion) all rights to payment under such invoices.

(d) Formatting and Requirements of Invoices. All invoices shall be submitted in the form attached hereto as Exhibit D, as it may be modified by HELUNA HEALTH from time to time.

6. TERM AND TERMINATION

(a) Term. Unless earlier terminated as provided herein, the term of this Agreement shall be from September 7, 2023 to September 6, 2025 (the "Term").

(b) Termination Without Cause. Reserved.

(c) Termination for Cause. With reasonable cause, either party may terminate this Agreement effective immediately upon the giving of written notice of termination for cause. Reasonable cause shall include:

i. A material violation or breach of this Agreement by the other party which is not cured within 15 days after written notice from the terminating party;

ii. Any act of the other party that exposes the terminating party to liability to others for personal injury or property damage or any other harm, damage or injury; or

iii. If either party receives notice from the Funding Agency of the cancellation or termination of, or reduction of funding under, the Funding Award Agreement affecting the Services.

(d) Termination for Lack of Funding. HELUNA HEALTH may terminate this Agreement if for any reason the funding available under the Funding Award Agreement is withdrawn, limited, or impaired.

(e) Cessation Upon Termination. On the effective date of termination, Subcontractor/Subawardee shall cease all further Services under this Agreement, and Subcontractor/Subawardee shall cancel as many outstanding obligations as possible and not incur any additional obligations.

(f) Payment After Termination. Subject to the terms and conditions set forth in this Agreement, upon termination of this Agreement, provided, that HELUNA HEALTH has received the corresponding funds from the Funding Agency under the Funding Award Agreement , HELUNA HEALTH shall pay for any reasonable non-cancellable obligations properly incurred by Subcontractor/Subawardee under this Agreement and in accordance with the Budget prior to termination, and shall pay any amounts due to Subcontractor/Subawardee and properly invoiced under this Agreement for Services performed prior to termination; provided, that if HELUNA HEALTH has terminated this Agreement for reasonable cause under Section 6(c) above, then HELUNA HEALTH shall have the right to offset and deduct from any payments due to Subcontractor/Subawardee hereunder any damages or losses incurred by HELUNA HEALTH as a result of such violation or breach.

(g) Return of Materials. Reserved.

(h) Surviving Provisions. The provisions of Sections 7 through 16, and any other sections that by their nature should or are intended to survive the expiration or termination of this Agreement shall survive and the parties shall continue to comply with the provisions of this Agreement that survive.

7. REPRESENTATIONS AND WARRANTIES. Subcontractor/Subawardee represents, warrants and covenants to HELUNA HEALTH as follows:

(a) Licenses and Permits. Subcontractor/Subawardee maintains and shall maintain during all relevant times under this Agreement all applicable federal, state and local business and other licenses, including any professional licenses or certificates, industrial permits and/or licenses, industry specific licenses, licenses required by the state(s) and/or locality(s) in which it does business, fictitious business names, federal tax identification numbers, insurance, and anything else required of Subcontractor/Subawardee as a business operator.

(b) Qualifications and Performance. Subcontractor/Subawardee (i) has the experience and skill to perform the Services hereunder, (ii) shall perform the Services in a good and workman like manner and in accordance with generally accepted professional standards and in an expeditious and economical manner consistent with sound professional practices, and (iii) is adequately financed to meet any financial obligation it may be required to incur hereunder.

(c) Not Debarred. Neither Subcontractor/Subawardee nor its principals or personnel are presently, nor will any of them be during the term of this Agreement, debarred, suspended,

proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or funding agency.

8. INDEPENDENT CONTRACTOR STATUS

(a) Independent Contractor. Nothing in this Agreement is intended to place the parties in the relationship of employer-employee, partners, joint venturors, or in anything other than an independent contractor relationship. It is the parties' intention that Subcontractor/Subawardee shall be an independent contractor and not HELUNA HEALTH's employee or agent, and in conformity therewith, that Subcontractor/Subawardee shall retain sole and absolute discretion and judgment in the manner and means of carrying out Subcontractor/Subawardee's Services hereunder. Subcontractor/Subawardee is under the control of HELUNA HEALTH as to the results of Subcontractor/Subawardee's Services only, and not as to the means by which such results are accomplished.

(b) No Power to Bind HELUNA HEALTH. Without limiting the generality of the foregoing paragraph, this Agreement does not designate Subcontractor/Subawardee as the agent or legal representative of HELUNA HEALTH for any purpose whatsoever. Subcontractor/Subawardee is not granted any right or authority to assume or create any obligation or responsibility, or to make any promise or commitment regarding any work, on behalf of or in the name of HELUNA HEALTH or to bind it in any manner, or to make any contract or agreement on behalf of or in the name of HELUNA HEALTH, without the prior written consent from HELUNA HEALTH management. No sales, invoices nor orders for goods or services shall be valid and binding upon HELUNA HEALTH (whether as the provider or the recipient) unless and until accepted by HELUNA HEALTH, at its sole and absolute discretion, through its established channels. HELUNA HEALTH shall not be liable for any obligation incurred by Subcontractor/Subawardee.

(c) No Withholding. Except for tax withholdings that are required by law, neither federal, nor state, nor local income tax nor payroll taxes of any kind shall be withheld or paid by HELUNA HEALTH on behalf of Subcontractor/Subawardee or the employees of Subcontractor/Subawardee. Subcontractor/Subawardee and its personnel shall not be treated as employees or HELUNA HEALTH with respect to the Services performed hereunder for federal or state tax purposes or for any other purposes.

(d) No Employee Benefits. Neither Subcontractor/Subawardee nor its personnel shall be eligible for, and shall not participate in, any of HELUNA HEALTH's retirement, health, or other fringe benefit plans.

(e) Workers' Compensation. No workers' compensation insurance shall be obtained by HELUNA HEALTH concerning Subcontractor/Subawardee or Subcontractor's/Subawardee's personnel. Subcontractor/Subawardee shall comply with all workers' compensation laws concerning Subcontractor/Subawardee and its personnel.

(f) Taxes. Subcontractor/Subawardee understands that Subcontractor/Subawardee is responsible to pay, according to law, Subcontractor's/Subawardee's income taxes. If Subcontractor/Subawardee is not an entity, Subcontractor/Subawardee further understands that Subcontractor/Subawardee may be liable for self-employment (social security) tax, to be paid by Subcontractor/Subawardee according to law. Subcontractor/Subawardee shall be solely responsible for the payment of all federal, state and local income taxes, social security taxes, federal and state unemployment insurance and similar taxes and all other assessments, taxes, contributions or sums payable with respect to Subcontractor/Subawardee or its employees as a result of or in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee represents and warrants and covenants that it shall report all income earned as a result of this Agreement and pay all federal, state and local income and self-employment taxes and other assessments required to be paid under applicable law. Subcontractor/Subawardee agrees to defend, indemnify and hold HELUNA HEALTH harmless from any and all claims made by federal, state and local taxing authorities on account of Subcontractor's/Subawardee's failure to pay any such federal, state or local income and self-employment taxes or other assessments due as a result of Subcontractor's/Subawardee 's Services hereunder.

(g) Sub-Tier Subcontractors/Subawardees. Subcontractor/Subawardee shall have control over the manner and means of Subcontractor/Subawardee's performance under this Agreement. However, HELUNA HEALTH is engaging Subcontractor/Subawardee for Subcontractor's/Subawardee's unique skills, knowledge, abilities and other attributes. Any lower-tier subcontractors/subawardees who are approved by HELUNA HEALTH must execute all agreements and documents required by HELUNA HEALTH prior to performing any work. Subcontractor/Subawardee shall ensure that all lower-tier subcontractors/subawardees comply with all of the terms and provisions of this Agreement and shall be responsible and liable for all acts and omissions of all lower-tier subcontractors/subawardees as if they were the acts or omissions of Subcontractor/Subawardee.

9. OWNERSHIP OF WORK PRODUCT

(a) Ownership of Work Product. Subcontractor/Subawardee owns all work product developed under this Agreement.

(b) No Infringement. Subcontractor/Subawardee represents and warrants that any Work Product developed by Subcontractor/Subawardee and shall not infringe or violate any patents, copyrights, trademarks, trade secrets or other proprietary rights of any third party.

(c) No Harmful Code. With respect to the website and any computer programs or software code ("Software") included in the Services hereunder, Subcontractor/Subawardee represents and warrants that: (i) the Software and its media shall contain no computer instructions or inappropriate functions whose purpose or result is to disrupt, damage or interfere with HELUNA HEALTH's or its affiliates' or their customers' use of or access to the Software or any of their data, programs or computer or telecommunications facilities and (ii)

unless expressly authorized in writing by HELUNA HEALTH, such Software shall not contain any mechanism which electronically notifies Subcontractor/Subawardee of any fact or event, nor contain any key, node lock, time-out, logic bomb or other function, implemented by any means, which may restrict HELUNA HEALTH's or its affiliates' or customers' use of or access to the Software or any other programs, data or equipment.

10. PUBLICATIONS

(a) Right to Publish Works. Subcontractor/Subawardee may, with HELUNA HEALTH's and the Funding Agency's prior written consent, publish articles written by Subcontractor/Subawardee in connection with the Services performed by Subcontractor/Subawardee hereunder. Subcontractor/Subawardee shall submit all such articles for review by HELUNA HEALTH and the Funding Agency at least 60 days prior to the proposed publication date.

(b) Acknowledgment in Publications. On any publication approved by HELUNA HEALTH and the Funding Agency as described above, Subcontractor/Subawardee shall place an acknowledgment of federal government support, and shall include a disclaimer, as appropriate, as follows: "The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of Heluna Health. or **[Name of Funding Agency]**".

(c) Use of HELUNA HEALTH's or Funding Agency's Name. Subcontractor/Subawardee shall not use in any manner HELUNA HEALTH's name, logo or trademarks without HELUNA HEALTH's prior written consent. Subcontractor/Subawardee shall not use in any manner the Funding Agency's name, logo or trademarks without the Funding Agency's prior written consent.

11. INDEMNIFICATION

HELUNA HEALTH hereby agrees to indemnify, hold harmless and defend Subcontractor/Subawardee, its officers, directors, agents, contractors and employees from any and all claims, causes of action, costs, demands, expenses (including attorney's fees and costs), losses, damages, injuries, and liabilities arising from (i) any accident, death, or injury whatsoever or however caused to any person or property arising out of the intentional action or negligence of HELUNA HEALTH, (ii) HELUNA HEALTH's violation of any federal, state or local law or regulation or (iii) the breach by HELUNA HEALTH of any its representations, warranties or agreements under this Agreement.

12. INSURANCE

Subcontractor/Subawardee shall, unless otherwise agreed in writing by HELUNA HEALTH, maintain: (i) Workers' Compensation insurance, (ii) Professional Liability Insurance and Commercial General Liability Insurance (including broad form contractual and automobile liability coverage), with minimum limits of ONE MILLION DOLLARS ($1,000,000) combined single

limit per occurrence, and (iii) Automobile Liability on each automobile owned by him/her/it or his/her/its agents, subcontractors/subawardees or employees, which is used at any time to carry out Subcontractor's/Subawardee's duties hereunder, with minimum limits of $100,000 per person and $300,000 per occurrence for bodily injury. If higher or additional coverages are required under the Flow Down Provisions, attached as Exhibit C, Subcontractor/Subawardee shall procure such coverages. A program of self-insurance is acceptable.

13. CONFIDENTIALITY

(a) Sunshine Ordinance. HELUNA HEALTH acknowledges that this Agreement and all records related to its formation, and the performance of Services, and HELUNA HEALTH's payment are subject to the California Public Records Act, (California Government Code §6250 et. seq.), and the San Francisco Sunshine Ordinance, (San Francisco Administrative Code Chapter 67). Such records are subject to public inspection and copying unless exempt from disclosure under federal, state or local law.

(b) Confidential Information. Confidential Information includes, but is not limited to, the identity of actual and potential clients of HELUNA HEALTH, client lists, particular needs of each client, the manner in which business is conducted with each client, addresses, telephone numbers, and specific characteristics of clients; Subcontractor/Subawardee shall not disclose in any manner whatsoever any of the aforesaid Confidential Information, directly or indirectly, or use it in any way whatsoever, either during this Agreement or at any time thereafter, except as required in the course of Subcontractor's/Subawardee's work with HELUNA HEALTH or except as otherwise provided in this Agreement or permitted by law. Further, Subcontractor/Subawardee shall develop and maintain procedures and take other reasonable steps in furtherance of HELUNA HEALTH's desire to maintain the confidentiality of its Confidential Information.

(c) Funding Agency Confidentiality. Subcontractor/Subawardee shall also comply with all confidentiality obligations imposed by the Funding Agency in the Funding Award Agreement, if attached as Exhibit C.

14. RECORD RETENTION AND ACCESS TO RECORDS

Subcontractor/Subawardee shall grant to HELUNA HEALTH, the Funding Agency and the U.S. Comptroller General and their respective authorized representatives upon demand, access to any books, documents, papers and records of Subcontractor/Subawardee relating to this Agreement or the Services for audit, examination, excerpt and transcription. Subcontractor/Subawardee shall retain all such records for seven (7) years (or longer if required under HELUNA HEALTH's record retention policy, under the Funding Award Agreement or by law, including under Circular A-110, Subpart C, Post-Award Requirements and FAR Subpart 4.7 Contractor Records Retention - 4.703 Policy) after final payment is made under this Agreement and all pending matters are closed, unless extended by an audit, litigation, or other action involving the records, whichever is later.

15. GENERAL TERMS

(a) Amendments. Amendments to this Agreement shall be in writing, signed by the party to be obligated by such amendment and attached to this Agreement.

(b) Governing Law; Venue. This Agreement shall be interpreted, construed and governed by, in accordance with and consistent with the laws of the State of California with venue in San Francisco.

(c) Equitable Relief. In light of the irreparable harm to HELUNA HEALTH that a breach by Subcontractor/Subawardee of Sections 9, 10, 13 and 14 of this Agreement would cause, in addition to other remedies set forth in this Agreement and other relief for violations of this Agreement, HELUNA HEALTH shall be entitled to enjoin Subcontractor/Subawardee from any breach or threatened breach of such Sections, to the extent permitted by law and without bond.

(d) Binding Agreement. All terms, conditions and covenants to be observed and performed by the parties hereto shall be applicable to and binding upon their respective agents, employees, heirs, executors, administrators, affiliates, subsidiaries, associates, employees, successors and assigns.

(e) Captions. All captions (section headings) set forth herein are inserted only as a matter of convenience and for reference, and shall not affect the interpretation of this Agreement.

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which, when taken together, shall constitute one and the same document.

(g) Additional Documents. The parties hereto each agree that they shall execute and, if appropriate, acknowledge any and all additional and other documents, instruments and writings which may be reasonably requested by the other party in order to fully carry out the intent and purpose of this Agreement.

(h) Entire Agreement. This Agreement, and all documents referred to in it, or incorporated in it, is an integrated document containing and expressing all terms, covenants, conditions, warranties and agreements of the parties relating to the subject matter hereof. No other or prior agreements or understandings, written or oral, pertaining to the same shall be valid or of any force or effect.

(i) Facsimile or Email Transmissions. A facsimile transmission or transmission by Email of the executed signature page of this Agreement shall be accepted as, relied upon as, and deemed to be, an original.

(j) Fair Interpretation. The language appearing in all parts of this Agreement shall be construed, in all cases, according to its fair meaning in the English language, and not strictly construed for or against any party hereto. This Agreement has been prepared jointly by the parties hereto after arm's length negotiations and any uncertainty or ambiguity contained in this Agreement, if any, shall not be interpreted or construed against any party, but according to its fair meaning applying the applicable rules of interpretation and construction of contracts.

(k) No Waiver. No failure or delay by any party in exercising a right, power or remedy under the Agreement shall operate as a waiver of any such right or other right, power or remedy. No waiver of, or acquiescence in, any breach or default of any one or more of the terms, provisions or conditions contained in this Agreement shall be deemed to imply or constitute a waiver of any other or succeeding or repeated breach or default hereunder. The consent or approval by any party hereto to or of any act of the other party hereto requiring further consent or approval shall not be deemed to waive or render unnecessary any consent or approval to or of any subsequent similar acts.

(l) Notices. Any notice, demand, consent or other communication required or permitted to be given hereunder shall be made in the English language and shall be so given by personal delivery, by (i) registered or certified (return receipt) or First Class United States Postal Service mail, postage pre-paid, or (ii) recognized overnight national courier service, or (iii) facsimile transmission confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, or (iv) by email confirmed by letter sent by First Class United States Postal Service mail, postage pre-paid, addressed to the recipient of such notice at the following address or facsimile number, as the case may be, or any other address or facsimile number or email address provided by a party in the manner described hereinabove:

In the case of HELUNA HEALTH, addressed to:

Heluna Health
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746-3505
Attention: Adam Abate
Facsimile: (562) 692-6950
Email: AAbate@helunahealth.org

In the case of Subcontractor, addressed to:

San Francisco Department of Public Health
1380 Howard Street
San Francisco, CA 94103
Attention: Sajid Shaikh
Facsimile: (415) 503-4710
Email: Sajid.shaikh@sfdph.org

And

San Francisco Department of Public Health
101 Grove Street, Room 410
San Francisco, CA 94102
Attention: Contract Analyst
Facsimile: (415) 554-2555
Email: DPH-ContractsRm410@sfdph.org

Any such notice shall be deemed to have been received by the addressee, and service thereof shall be deemed effective, five (5) days following deposit thereof with the United States Postal Service, or upon actual receipt, whichever first occurs, unless the address for delivery is not within one of the United States or its territories or possessions, in which case service shall be effective seven (7) days following deposit, or upon actual receipt, whichever first occurs.

(m) Remedies Non-Exclusive. Except where otherwise expressly set forth herein, all remedies provided by this Agreement shall be deemed to be cumulative and additional and not in lieu of or exclusive of each other or of any other remedy available to the respective parties at law or in equity.

(n) Severability. If any term, provision, condition or other portion of this Agreement is determined to be invalid, void or unenforceable by a forum of competent jurisdiction, the same shall not affect any other term, provision, condition or other portion hereof, and the remainder of this Agreement shall remain in full force and effect, as if such invalid, void or unenforceable term, provision, condition or other portion of this Agreement did not appear herein.

(o) Limitation of Liability. EXCEPT FOR A BREACH OF SECTIONS 9 AND 13 ABOVE AND EXCEPT TO THE EXTENT INCLUDED IN A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11 ABOVE, IN NO EVENT SHALL ANY PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, AND WHETHER OR NOT THAT PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

(p) Non-Assignability. None of the parties shall assign, transfer, sell, encumber, hypothecate, alienate or otherwise dispose of this Agreement, or any right, title or interest to or in this Agreement, nor shall a party delegate any duty or obligation to be performed hereunder, without the express written consent of the other party having been first obtained, except that any party may assign this Agreement without the consent of the other party in the case of a reorganization, merger, consolidation, or sale of all or substantially all of its assets so long as the assignee expressly assumes all of the obligations of the assignor under this Agreement. Notwithstanding the foregoing, HELUNA HEALTH may assign this Agreement to an

affiliate of HELUNA HEALTH without the consent of the other party. Any attempt to assign this Agreement other than as permitted above shall be null and void.

(q) Signing Person. The individuals signing this Agreement on behalf of an entity represents and warrants that he/she has authority to bind such entity to this Agreement.

[Signatures follow on next page]

The undersigned have caused this Subcontract/Subaward Agreement to be executed as of the date first set forth above:

HELUNA HEALTH

By: DocuSigned by: Rochelle McLaurin 11FA7C5B062940D... Date: 04/29/2024 | 5:01 PM PDT

Rochelle McLaurin
Chief Program Officer
Director, Contract and Grant Management

THE CITY AND COUNTY OF SAN FRANCISCO

By: DocuSigned by: Naveena Bobba 52BC36E46CB9439... Date: 04/30/2024 | 11:08 AM PDT

Grant Colfax, MD
Director of Health
Department of Public Health

Approved as to Form

David Chiu
City Attorney

By: DocuSigned by: Henry Lifton 6D6CB58424584B1... Date: 04/29/2024 | 10:50 PM PDT

Henry Lifton
Deputy City Attorney

Exhibits

Exhibit A: Scope of Work (SOW)
Exhibit B: Budget
Exhibit C: Flow Down Provisions
Exhibit D: Form of Invoice
Exhibit E: Certificate of Self Insurance

EXHIBIT A
TO SUBCONTRACT/SUBAWARD AGREEMENT

SCOPE OF WORK (SOW)

Susan Buchbinder, MD (Principal Investigator):
As Principal Investigator (PI) of this proposal, she will be responsible for the overall scientific vision and implementation of the specific aims of this study. Dr. Buchbinder will have responsibility for maintaining the proposed study schedule, ensuring quality control over all aspects of the study, protecting participant safety, and data analysis and publication of results.

Albert Liu, MD, MPH (Co-Investigator):
Dr. Liu will be responsible for overseeing technology development with our web developer, who will be adapting the MyPrEP website. He will also assist with scientific design of research protocols. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through in-person meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results.

Hyman Scott, MD, MPH (Co-Investigator):
He will provide overall operational oversight of the clinical research team at Bridge HIV. He will maintain frequent contact with Dr. Buchbinder and the other Co-Investigators through in-person meetings, conference calls, e-mail, and drafting and presenting emerging findings of the research. He will also work closely with the research team in data analysis, manuscript preparation, and dissemination of results.

EXHIBIT B
TO SUBCONTRACT/SUBAWARD AGREEMENT
BUDGET

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 09/07/23	THROUGH 09/06/25	
List PERSONNEL *(Applicant organization only)* Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits								
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Susan Buchbinder	PD/PI	3.60			212,100	63,630	23,543	87,173
Albert Liu	Co-PI	1.20			212,100	21,210	7,848	29,058
Hyman Scott	Co-PI	1.20			212,100	21,210	7,795	29,005
						0	0	0
	SUBTOTALS					106,050	39,186	145,236
CONSULTANT COSTS								
								0
EQUIPMENT *(Itemize)*								
								0
SUPPLIES *(Itemize by category)*								
								0
TRAVEL	0							
								0
INPATIENT CARE COSTS								0
OUTPATIENT CARE COSTS								0
ALTERATIONS AND RENOVATIONS *(Itemize by category)*								
								0
OTHER EXPENSES *(Itemize by category)*								
								0
CONSORTIUM/CONTRACTUAL COSTS								0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*							DIRECT COSTS	**145,236**
CONSORTIUM/CONTRACTUAL COSTS				22.46%			FACILITIES AND ADMINISTRATIVE COSTS	32,623
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								**177,860**

Total budget not to exceed $177,860.

EXHIBIT C
TO SUBCONTRACT/SUBAWARD AGREEMENT

FLOW DOWN PROVISIONS

Refer to the following pages.

Docusign Envelope ID: 878C1F25-FF3E-40BB-90B5-AGG2E062A96E

Recipient Information

1. Recipient Name
PUBLIC HEALTH FOUNDATION ENTERPRISES, INC.
13300 CROSSROADS PKWY N
STE 450
CITY OF INDUSTRY, CA 91746

2. Congressional District of Recipient
32

3. Payment System Identifier (ID)
1952557063A1

4. Employer Identification Number (EIN)
952557063

5. Data Universal Numbering System (DUNS)
082199324

6. Recipient's Unique Entity Identifier
L4EEW9SQX2F6

7. Project Director or Principal Investigator
Susan Buchbinder, MD
Director
Susan.Buchbinder@sfdph.org
628-217-7479

8. Authorized Official
Adam Abate
aabate@helunahealth.org
562-222-7804

Federal Agency Information

9. Awarding Agency Contact Information
Julie M. Bergerud
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH
julie.bergerud@nih.gov
301-827-6184

10. Program Official Contact Information
Michael J Stirratt
Chief, Adherence To Treatment & Prevention Program And Hiv Small Business Program (sbir/sttr)
NATIONAL INSTITUTE OF MENTAL HEALTH
stirrattm@mail.nih.gov
240-627-3875

Federal Award Information

11. Award Number
1R34MH132405-01

12. Unique Federal Award Identification Number (FAIN)
R34MH132405

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
MyPrEP Plus: Development and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women

15. Assistance Listing Number
93.242

16. Assistance Listing Program Title
Mental Health Research Grants

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/07/2023 **– End Date** 09/06/2025	
20. Total Amount of Federal Funds Obligated by this Action	$521,875
20 a. Direct Cost Amount	$482,440
20 b. Indirect Cost Amount	$39,435
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$521,875
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$521,875
26. Project Period Start Date 09/07/2023 **– End Date** 09/06/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$521,875

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Christine Clarkson

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R34MH132405-01

Principal Investigator(s):
Susan Buchbinder, MD

Award e-mailed to: pdale@helunahealth.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $521,875 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to PUBLIC HEALTH FOUNDATION ENTERPRISES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R34MH132405. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Christine Clarkson
Grants Management Officer
NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
Federal Direct Costs	$482,440
Federal F&A Costs	$39,435
Approved Budget	$521,875
Total Amount of Federal Funds Authorized (Federal Share)	$521,875
TOTAL FEDERAL AWARD AMOUNT	$521,875
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$521,875

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$521,875	$521,875

Fiscal Information:

Payment System Identifier:	1952557063A1
Document Number:	RMH132405A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023
MH	8472592	$521,875

NIH Administrative Data:
PCC: 9A-ASGA / **OC**: 41021 / **Released**: Clarkson, Christine 08/30/2023
Award Processed: 09/07/2023 12:06:30 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34MH132405-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R34MH132405-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

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d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

MULTI-YEAR FUNDED AWARD: This is a multi-year funded award. A progress report is due annually on or before the anniversary of the budget/project period start date of the award, in accord with the instructions posted at: http://grants.nih.gov/grants/policy/myf.htm.

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R34MH132405. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated

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funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by

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persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS – 1R34MH132405-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

RESTRICTION - HUMAN SUBJECTS:

In the absence of certification of IRB approval for Aim 3 for this project, this award is issued with the following restriction: only activities that are clearly severable and independent from Aim 3 activities that involve human subjects may be conducted under this award until the project has received IRB approval consistent with 45 CFR Part 46, and certification of IRB approval has been submitted to and accepted by the National Institute of Mental Health (NIMH). Failure to comply with this term may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

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Funds included in this award for research involving human subjects in Aim 3 in this project are restricted pending acceptance of certification of IRB approval for Aim 3 by the NIMH. Funds will not be available for carryover under the expanded authorities or Federal Demonstration Partnership without the written prior approval of the NIMH. In addition, no funds may be drawn down from the Payment Management System or expended for any research involving human subjects until the NIMH has accepted the certification of IRB approval.

AWARD NOTICE:
This award has been made in response to the application submitted under the Funding Opportunity Announcement PA-20-141 which can be referenced at: PA-20-141: Formative and Pilot Intervention Research for Prevention and Treatment of HIV/AIDS (R34 Clinical Trial Optional) (nih.gov)

CHANGE TO A MULTIYEAR FUNDED AWARD:
Although the application was submitted as a 2-year grant request, in order to meet Institute program priorities and objectives within Fiscal Year 2023, this grant has been converted to a multi-year funded award, with all years of funding provided in the current fiscal year. Special monitoring requirements specific to multiyear funded awards, including the progress report due on or before the anniversary of the budget/project period start date of the award, are detailed in Section III in this Notice of Award.

MULTI-YEAR FUNDED REQUIREMENT:
This grant may be deemed materially non-compliant if annual RPPRs are not submitted on September 1st each year. Further enforcement actions may be necessary in accordance with the NIH Grants Policy Statement Section 8.5 (http://grants.nih.gov/grants/policy/nihgps/index.htm).

CONSORTIUM / CONTRACTUAL COSTS:
This award includes funds for consortium activity with **Department of Public Health, City and County of San Francisco (DPH/CCSF).**

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

PARTICIPANT RECRUITMENT - MILESTONES:
Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on 6/20/23. It is expected that 60 of the 60 total projected participants will be recruited by 8/1/25. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at: http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

DATA AND SAFETY MONITORING: Study ID 419992
This grant is subject to the clinical research policies outlined in NOT-MH-19-027. The recipient will adhere to the NIH (NIH GPS 4.1.15) and NIMH policies (NOT-MH-19-027) including appropriately providing adequate data and safety monitoring and timely reporting of key events

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as defined in the NIMH Reportable Events Policy. The level and frequency of human subject data and safety monitoring should always be commensurate with the risk and nature of the research.

Each RPPR submitted is expected to include, in Section **G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS**, a summary of key safety indices (e.g., cumulative rates of AEs/SAEs) during the reporting period and cumulatively over the course of the project; and a summary of any safety recommendations from the IRB reviews and any actions taken based on the recommendations.

GCP TRAINING:
NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:
The clinical trial(s) supported by this award is subject to the plan within the competing application dated 5/4/22 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:
This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:
In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

HUMAN SUBJECTS RESEARCH:
This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

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SPREADSHEET SUMMARY
AWARD NUMBER: 1R34MH132405-01

INSTITUTION: PUBLIC HEALTH FOUNDATION ENTERPRISES

Budget	Year 1
Salaries and Wages	$136,657
Fringe Benefits	$45,595
Personnel Costs (Subtotal)	$182,252
Consultant Services	$5,200
Equipment	$3,400
Other	$77,310
Subawards/Consortium/Contractual Costs	$177,778
Participant Stipends	$36,500
TOTAL FEDERAL DC	$482,440
TOTAL FEDERAL F&A	$39,435
TOTAL COST	$521,875

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	11%
F&A Cost Base 1	$148,920
F&A Costs 1	$16,381
F&A Cost Rate 2	13%
F&A Cost Base 2	$147,557
F&A Costs 2	$19,182
F&A Cost Rate 3	13%
F&A Cost Base 3	$29,784
F&A Costs 3	$3,872

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EXHIBIT D
TO SUBCONTRACT/SUBAWARD AGREEMENT

FORM OF INVOICE

Please send monthly invoices to Tyler Norgord at TNorgord@helunahealth.org.

The final invoice must be marked FINAL.

The final invoice is due by October 5, 2025.

EXHIBIT E
TO SUBCONTRACT/SUBAWARD AGREEMENT

CERTIFICATE OF INSURANCE

Refer to the following page.

Docusign Envelope ID: 878C1F25-FF3E-40BB-90B5-AGC2E062A96E

City & County of San Francisco
London N. Breed, Mayor

Office of the City Administrator
Carmen Chu, City Administrator
Matt Hansen, Director, Risk Management

March 20, 2024

Heluna Health
Attn: Adam Abate
13300 Crossroads Parkway North, Suite 450
City of Industry, CA 91746-3505

RE: MyPrEP Plus: Debelopment and Pilot Testing of Novel Pre-Exposure Prophylaxis Support Tools for Transgender Women
Program/CID # 1067.0101

This letter certifies that the City and County of San Francisco is self-insured and self-funded for the following insurance coverages, which cover clinicians with the Department of Public Health listed on the attached schedule.

General Liability insurance in the amount of $1,000,000 per occurrence and $2,000,000 general aggregate for bodily injury, property damage, and personal injury to third parties for liability arising out of the City's negligence in performance of this agreement.

Automobile Liability insurance with limits not less than $1,000,000 combined single limit per accident for bodily injury and property damage including owned, and non-owned and hired auto coverage as applicable.

Workers' Compensation in statutory amounts with Employer's Liability of $1,000,000 per accident, injury or illness.

Professional Liability including Medical Malpractice and Errors & Omissions with limits not less than $1,000,000 each claim.

The City and County of San Francisco's self-insurance program is not commercial insurance and has no legal capacity to name another entity as additional insured.

Sincerely,

Matt Hansen
Director

cc: Brett Poe, SFDPH

EXHIBIT C



03/20/2025

Peter Dale
PUBLIC HEALTH FOUNDATION ENTERPRISES
pdale@helunahealth.org

Dear Peter Dale:

Effective with the date of this letter, funding for Project Number 5R01MH119956-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 04/26/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S
Date: 2025.03.20 12:02:04 -04'00'

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT D

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

March 24, 2025

William McFarland, MD
Professor
SHINE Strong: Building the pipeline of HIV behavioral scientists with expertise in trans population health
SFDPH Center for Public Health Research
25 Van Ness Ave Suite 500
San Francisco, CA 94102
Willi_mcfarland@hotmail.com

Subject: Termination Letter: Notification of Termination

Dear William McFarland,

We are writing to formally notify you that Heluna Health received a termination letter from National Institutes of Health on Friday, March 21, 2025 for Contract 5R25MH119858-05 (HH Project # 0761.0105) to cease all activities associated with this project effective March 21, 2025.

Cost resulting from financial obligations incurred after termination of this project are not allowable. To comply with this termination, Heluna Health is initiating the closeout requirements for this project.

To facilitate the closeout process, your client support team will schedule a meeting with you to discuss the steps for closeout, such as staff time allocation; vendor management; final report; expenditures; equipment; etc.

Even though this is one project in your portfolio of projects, we understand the impact this termination can have on the staff and the clients that you have supported, built relationships with as well as, providing services that created health and well-being in our communities throughout California.

We value your contributions, and we look forward to our continued partnership.

Should you have any questions about this letter, please contact Adam Abate at aabate@helunahealth.org and 562-222-7804.

Please acknowledge receipt of this termination letter by signing below and returning a copy to us by March 25,2025.

Thank you for your cooperation and understanding.

Sincerely,

DocuSigned by:
Blayne Cutler
849ACF087DB74D2...
Blayne Cutler, MD
Chief Executive Officer

CC:
Rochelle McLaurin
Johnson Troung

Heluna Health
EMPOWERING POPULATION HEALTH INITIATIVES SINCE 1969

Shelia Elahee
Adam Abate

Acknowledgement:

Willi McFarland

Print Name and Title

Willi McFarland 25 March 2025

Signature and Date

EXHIBIT E

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

February 28, 2025

Maria G. Diaz
The Regents of the University of California, Irvine
160 Aldrich Hall
Irvine, CA 92697-7600

Dear Ms. Diaz,

Funding for Project Number 5DP2AI164315-04 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/06/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5DP2AI164315-04 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.

You must submit a request for such review to Dr. Matthew J. Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Matthew J. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Emily B. Linde -S

Digitally signed by Emily B. Linde -S
Date: 2025.02.28 17:35:13 -05'00'

Emily Linde

Director, Grants Management Program
National Institutes of Allergy and Infectious Diseases

[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT F



03/20/2025

PETER DAVID DALE
PUBLIC HEALTH FOUNDATION ENTERPRISES
pdale@helunahealth.org

Dear PETER DAVID DALE:

Effective with the date of this letter, funding for Project Number 5R01MH128049-04 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/30/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer,
National Institute of Mental Health
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT G



March 18, 2025

Olive T. Giovannetti
The Regents of the University of California, San Francisco
Olive.giovannetti@ucsf.edu

Dear Olive T. Giovannetti:

Effective with the date of this letter, funding for Project Number 1R01 AI181732-01A1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on July 18, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.
[6] 2024 Policy Statement at IIA-156.

agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov.*[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.19 21:54:59 -04'00'

Michelle G. Bulls, on behalf Emily Linde, Chief Grants Management Officer, National Institute of Allergy and Infectious Diseases
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D
[11] 11 *Id.* § 50.406(a)
[12] 12 *Id.* § 50.406(b)

EXHIBIT H

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# UM2HD111102
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
FLORIDA STATE UNIVERSITY
874 TRADITIONS WAY
TALLAHASSEE, FL 32306

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1596001138A1

4. Employer Identification Number (EIN)
596001138

5. Data Universal Numbering System (DUNS)
790877419

6. Recipient's Unique Entity Identifier
JF2BLNN4PJC3

7. Project Director or Principal Investigator
Lisa B Hightow-Weidman, MD (Contact)
Professor
lhightowweidman@fsu.edu
850-644-3296

8. Authorized Official
Stacey Patterson

Federal Agency Information

9. Awarding Agency Contact Information
Mahasin Ingram

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
ingrammk@mail.nih.gov
(201) 780-0309

10. Program Official Contact Information
Denise Russo
Program Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
drusso1@mail.nih.gov
301-435-6871

Federal Award Information

11. Award Number
5UM2HD111102-03

12. Unique Federal Award Identification Number (FAIN)
UM2HD111102

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR Part 52

14. Federal Award Project Title
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Scientific Leadership Center

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$11,647,748
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$11,647,748
26. Project Period Start Date 01/25/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$36,023,354

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

Cooperative Agreement
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5UM2HD111102-03 REVISED

Principal Investigator(s):
Lisa B Hightow-Weidman (contact), MD
Sybil Hosek, PHD

Award e-mailed to: SRA-Pre@fsu.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to FLORIDA STATE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR Part 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UM2HD111102. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Margaret A. Young
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	$829,730
Fringe Benefits	$266,026
Personnel Costs (Subtotal)	$1,095,756
Consultant Services	$387,198
Materials & Supplies	$44,168
Travel	$56,400
Other	$2,104,186
Subawards/Consortium/Contractual Costs	$5,908,978
ADP/Computer Services	$30,000
Federal Direct Costs	$9,626,686
Federal F&A Costs	$2,021,062
Approved Budget	$11,647,748
Total Amount of Federal Funds Authorized (Federal Share)	$11,647,748
TOTAL FEDERAL AWARD AMOUNT	$11,647,748
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$11,647,748	$11,647,748

Fiscal Information:

Payment System Identifier:	1596001138A1
Document Number:	UHD111102A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
HD	8014710	$8,647,748
MH	8472592	$1,000,000
DA	8472628	$2,000,000

NIH Administrative Data:
PCC: MPIDB-DR / **OC**: 41029 / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:22:50 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM2HD111102-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5UM2HD111102-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) UM2HD111102. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines. This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to

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Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) National Institute On Drug Abuse (NIDA) National Institute Of Mental Health (NIMH)

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently

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the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5UM2HD111102-03 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

TERMINATION

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

CLOSEOUT

"Recipient Institution" may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable within 120 days of the end of this grant.

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.

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- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

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

****

RESTRICTION: This award is being made without a currently valid certification of Institutional Review Board (IRB) approval and is issued with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval. No funds may be drawn down from the Payment Management System and no obligations may be made against Federal funds for any research involving human subjects prior to issuance of a revised Notice of Award rescinding this restriction.

IRB approval verification must be submitted within 60 days of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2022 and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice NOT-OD-06-054.

SUBPROJECT: Subproject funding information is available via the NIH RePORTER System.

HUMANS: For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice NOT-HD-20-036 “NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research”. All NICHD applications which include Clinical Trials must include a Data Safety

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Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice NOT-HD-20-035 "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

DISSEMINATION: The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the application dated 11/05/2022 and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of their knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

RISK ASSESSMENT:

Clinical Trial Study/Studies:

416802

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416804

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416806

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual

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RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

Clinical Trial Study/Studies:

416813

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **HIGH** risk requiring increased oversight by NICHD. A **quarterly update** on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones are due **three times a year** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416814

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **MEDIUM** risk requiring increased oversight by NICHD. An update on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones will be due **once a year (generally halfway through the budget period)** as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Clinical Trial Study/Studies:

416815

This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

SPREADSHEET SUMMARY
AWARD NUMBER: 5UM2HD111102-03 REVISED

INSTITUTION: FLORIDA STATE UNIVERSITY

Budget	Year 3
Salaries and Wages	$829,730
Fringe Benefits	$266,026
Personnel Costs (Subtotal)	$1,095,756
Consultant Services	$387,198
Materials & Supplies	$44,168
Travel	$56,400
Other	$2,104,186
Subawards/Consortium/Contractual Costs	$5,908,978
ADP/Computer Services	$30,000
TOTAL FEDERAL DC	$9,626,686
TOTAL FEDERAL F&A	$2,021,062

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TOTAL COST	$11,647,748

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	54%
F&A Cost Base 1	$3,742,708
F&A Costs 1	$2,021,062

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EXHIBIT I

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:31 AM
To: Sit, Jimmy <Bao.Sit@ucsf.edu>
Subject: Grant Termination Notification

This Message Is From an External Sender

This message came from outside your organization.



3/21/2025

Bao Sit
University Of California, San Francisco
bao.sit@ucsf.edu

Dear Bao Sit:

Effective with the date of this letter, funding for Project Number 5R25MH129290-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Theresa Jarosik, Chief Grants Management Officer, NIMH
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT 36

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF THERESA A. MALDONADO

I, Theresa A. Maldonado, declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the system-wide Vice President for Research & Innovation at the University of California (UC), Office of the President. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UC staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I have served as the Vice President for Research & Innovation at UC since 2020. In addition to my current role, I have a Ph.D. in electrical engineering and over 30 years' academic experience. As Vice President for Research & Innovation, I lead UC researchers and administrators in research policy, funding for systemwide programs, and the innovation and entrepreneurship ecosystem. We work to build UC-wide partnerships, help shape effective

policies and provide a strong voice nationally for research and innovation on behalf of UC. As the systemwide leader for research and innovation, I work very closely with the Vice Chancellors for Research from each UC campus, and I am in regular contact with them to identify any issues impacting UC systemwide research, including concerns related to research funding.

UC and Its Research Mission.

4. The University of California ("UC") has 10 research-intensive campuses, 21 health professional sciences schools, five NCI-designated cancer centers, and six academic medical centers are widely recognized as among the best in the nation. They are international leaders in the education of health professionals, in research that develops new cures and treatments, and in public service that provides healthcare for all Californians regardless of ability to pay. The University of California is one of the nation's leading research institutions, with almost 9% of all U.S. academic research being conducted by UC researchers. Biomedical advancements at UC include the first radiation treatment for cancer, research contributing to the first flu vaccine, the discovery of the role of LDL and HDL cholesterol in heart disease, the invention of modern gene editing, and much more.

5. Every year, UC and its researchers submit thousands of grant applications for review, approval, and funding by the NIH. As world leading researchers, more than 1,000 UC faculty members serve annually on numerous NIH study sections and advisory councils to assess grant applications for scientific and technical merit. NIH contract and grant funding support many of the clinical trial studies at UC's six medical centers.

6. The research mission at UC includes, but is not limited to, allocated funding for staffing, clinical trials, dissemination of results, public outreach, teaching and training students

and others, equipment, and numerous other activities to fulfill the research mission and serve the people of California and the United States.

Reliance on NIH Funding

7. In fiscal year 2024, UC was awarded over $2 billion through the National Institutes of Health ("NIH") to support more than 5000 research projects.

8. The work done by UC's research-intensive campuses, academic medical centers, and health professional sciences schools on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs.

9. UC's campuses, academic medical centers, health professional schools, cancer centers and the laboratories it manages and operates provide considerable employment benefits in the Science, Technology, Engineering, Mathematics, and Medicine ("STEMM") workforce to the California economy. UC estimates that NIH funding supports thousands of employees at its medical centers and campuses, including clinical and professional staff, post-doctoral and graduate student researchers, laboratory technicians, and engineers.

Typical Process for NIH Grant Awards

10. The Sponsored Projects Office at each UC location works with researchers to submit grant applications and tracks grant applications and awards. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is

then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

11. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether to recommend a grant for funding is made. After the advisory council meets, the relevant institute's Director typically approves the recommended grants, and a Notice of Award is promptly issued confirming the grant will be funded.

12. The budget process at UC research institutions relies, in part, upon the NIH grant application, review, and approval cycle.

Delays and Irregularities in the Processing of NIH Grant Applications

13. Since late January 2025, UC has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or not scheduled, and grant application scoring has been significantly delayed.

14. The estimated value of just the NIH grant proposals that have been submitted for review by the five UC Health Centers as of December 31, 2024, and that have not yet been acted upon is approximately $563 million. Grant applications awaiting study sections before July 1, 2025, had an annual value of approximately $312 million, while grant applications awaiting NIH advisory councils and Notices of Awards amounted to approximately $251 million in annualized value.

15. UC has not received formal notices of awards for many of these grant proposals. For others, UC has only received a notification that proposals are "paused" or "under review."

Terminations of NIH Grants.

16. Since February 20, 2025, UC's research institutions have had at least thirty-one NIH grants terminated, amounting to over $37 million. Among these was a grant for over $50 million in funding for a UC Davis research project investigating the biological risk factors for dementia among target populations with early signs of cognitive dysfunction, including white, Hispanic, and black participants that had already enrolled over 1,700 participants, and a grant to UCSF for a project studying the effectiveness and adverse consequences of a vaccine for shingles, a disease that one in three Americans are likely to develop in their lifetimes.

17. The termination notices for these grants typically state that the "award no longer effectuates agency priorities." In my time at UC, to the best of my knowledge, NIH grants have not generally been terminated on this basis.

18. Many of the termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, most UC Principal Investigators were not given notice of any opportunity to submit "corrected" grant materials to align with agency priorities.

Impacts of Funding Delays and Grant Terminations.

19. The delays in funding decisions and evaluation of grant applications as well as the grant terminations have already caused numerous and critical harms to UC.

20. The delays and terminations have disrupted ongoing research, as well as setting back significant UC research projects. Funding gaps have forced researchers to abandon important research studies and terminate key personnel. Some of these studies involve clinical trials of medications or procedures, and terminations will delay UC's ability to identify and

deliver life-changing care for patients suffering from diseases such as Alzheimer's disease, Type 2 Diabetes, and HIV.

21. Once canceled, much research cannot immediately resume. Many of these projects entail longitudinal studies. When scientific studies stop in full swing, their partial results often lose validity. Without funding, labs languish, and specimens spoil. And once laid off, people with project-specific knowledge and experience may not return.

22. The UC system has instituted a system-wide hiring freeze on new faculty and staff. Top-ranked departments across UC campuses in chemistry, biology, public health, and more have reduced their graduate student classes. UC departments have had to consider rescinding offers of funding to some students admitted to doctoral programs. To the extent possible, UC has arranged for emergency funding to cushion the impact of interrupted federal funding and maintain salary support for affected graduate students and trainees. This relief is aimed at bridging those personnel to give them time to complete their graduate programs or to secure other funding or employment.

23. These funds are being diverted from other important needs, such as deferred maintenance and strategic investments. Without expected grant funds, UC will be challenged in meeting the expenses associated with overseeing research facilities which make these significant research projects possible and economically viable.

24. The delays in funding and terminations also have harmed the UC's educational and research mission. Doctoral students, postdoctoral researchers, faculty, and staff from around the world collaborate with or come to California to join the UC research enterprise. Future recruitment of these young scientists and researchers will be negatively impacted by diminished funding and arbitrary terminations aimed at international collaboration and research projects.

Further, terminations have specifically impacted the communities that come to UC for clinical trials and other community health interventions. Midstream terminations of long-term projects meant to reduce health disparities in projects like maternal mortality, the spread of HIV/AIDS, and services to other underserved communities directly undermines the trust necessary to convince individuals to participate in UC research projects.

April 3, 2025

DocuSigned by:
Theresa A Maldonado
537FE71B2CD94F8...

THERESA A. MALDONADO

EXHIBIT 37

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

Background

1. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I served as director of NIGMS from 2003 to 2011. The purpose of NIGMS is to support research and training of scientists across a wide range of areas, including biochemistry, cell biology, genetics, computational biology, bioinformatics, anesthesiology, wound healing, and burn and trauma research. The United States' ability to effectively treat, diagnose, manage, and ultimately cure diseases requires an understanding of their underlying mechanisms and biology. NIGMS' investments in fundamental basic research have supported 90 Nobel prizes and improvements in treatments for diseases including heart disease, cancer, neurological diseases associated with aging, sepsis, and many others.

2. Throughout my career, I have also helped guide scientists at the beginning of their independent careers as they sought to compete for NIH funding. Prior to coming to NIH, I was Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins

University School of Medicine. In this role, I conducted research in partnerships with graduate students including combined MD/PhD students, and postdoctoral fellows with much of this work supported by NIGMS and other NIH institutes.

3. In 2011, I left NIH in 2011 to come to the University of Pittsburgh with my wife, a leading breast cancer screening expert who was recruited to this institution. Here, I have continued to conduct some NIH-funded research in the area of computational biology and also have helped to manage a range of programs that receive NIH funding.

4. Since January 20, 2025, delays and terminations in NIH funding have dramatically disrupted the work of advancing biomedical research and training the next generation of scientists. Steps that have contributed to these disruptions have included the "pausing" of grant-making processes at NIH, the extremely slow release of continuing awards for multi-year grants, the disruption of the regularly scheduled national Advisory Committee meetings required to approve grant applications prior to funding, the disruption of the peer review "study section" meetings required for grant application evaluation and prioritization, and other steps. More recently, these have included direct terminations of specific grants based not on lack of performance or any other irregularities, but claims that the aims of these grants no longer aligned with NIH's priorities.

5. Based on my personal analysis of publicly available data (through the NIH Reporter website), over $3.3 billion of NIH funding that would typically have been disbursed through NIH's grant making and grants management process by this point in the year has not been. Through March 1st, more than $1.8 billion of the funding is missing from the normal funding of continuation awards for multi-year grants. Similarly, more than a billion of the

funding is missing in new grant funding from grant applications that undergo the highly competitive scientific peer review described below.

6. Similarly, scientific colleagues have received grant terminations that have completely upended the work of their research labs, staff, and students. For example, all the awards for the Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Potential have apparently been terminated. This program is intended to do preparatory work for viruses and other pathogens that might cause pandemics in the future; and again went through a competitive award process. These awards were terminated on the grounds that the COVID pandemic is over and, therefore, this research is no longer needed. It is hard for me to understand the logic of the termination of these forward-looking looking grants when the risk of a pandemic from COVID and other viruses persist.

7. As further described below, these disruptions and terminations are completely contrary to my previous experience both at and with the National Institutes of Health.

Role of NIH in Biomedical Research at Universities

8. Since the 1930s, the NIH and its predecessor agencies have supported the advancement of the United States' understanding of human disease and disability by funding training and research. In 1944, Congress formally created the NIH as part of the Public Health Service in order to encourage scientific institutions, other public institutions, and scientists in the conduct of research and demonstrations related to the causes, diagnosis, treatment, control, and prevention of physical and mental illnesses and disability. Congress specifically authorized support of research through grants to universities, hospitals, laboratories, and other public or private institutions for research projects after review by the NIH institutes' national advisory

councils. Similarly, Congressional funding for training and fellowships dates back more than 50 years.

9. Since the 1930s, Congress has also added new institutes and centers focusing on different diseases, organ systems, life stages, or other aspects of biomedical research. For example, Congress specifically created NIGMS in 1962 to cover biomedical research of interest to two or more existing institutes or that are not covered by other institutes. Today, there are 27 institutes and centers as well as the Office of the Director within NIH. With the exceptions of the Center(s) for Scientific Review, the Center for Information Technology, and the NIH Clinical Center, the individual institutions, centers and the Director have the authority to issue grants to researchers through their organizations.

10. Today, Congress appropriates more than $47 billion to the NIH's institutes and centers to advance biomedical research, including through grants to extramural researchers and institutions. Over 85 percent of NIH's annual funding to advance biomedical research powers the more than 38,000 principal researchers, research projects, and trainees in external organizations across the United States.

11. NIH grants are typically awarded for an average of four years because the advancement of biomedical research benefits significantly from stable funding across a number of years. Very few research projects of any scientific significance can be completed in less than two years. Generally, grants are not fully funded all at once. An initial award in one fiscal year is followed by continuation (or non-competitive renewal) awards in subsequent years pending submission of an acceptable scientific and financial progress report. Thus, at any given point in time, about 80 percent of NIH's external funding is committed to existing research, support for the NIH intramural research program, or other costs such as NIH operations. The remaining 15

percent is available for new grant applications and the competitive renewal of long-term research projects. Stability is important to scientific investigation, particularly to encourage researchers to pursue innovation and risk in biomedical research. NIGMS has developed a variety of methods to provide stable funding for researchers so that productive or promising projects are not interrupted.

12. The stability of these grants also furthers the building of research capacity and the training of both graduate students and early-career scientists. A large proportion of pre- and postdoctoral scientists are supported during some or all of their training periods via research project grants rather than training awards. This situation exists because many members of research teams funded by NIH research project grants include graduate students and postdoctoral researchers who engage in research as a key component of their training activities.

13. Through the Ruth L. Kirschstein National Research Service Awards and other programs, Congress has historically directed funding to public and private institutions specifically for the pre-doctoral and post-doctoral training of individuals to undertake biomedical research. Since 1972, such funding has included explicit provisions directed toward increasing the percentage of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) into fields of biomedical research. This is particularly important since project selection and other aspects of research related to health can depend on the life experiences of those engaging in research.

14. At the direction of Congress, NIH and institutes like NIGMS have also increased their funding in specific research areas. For example, this is true for research related to HIV/AIDS which has been coordinated through the NIH Office of AIDS Research. When I was a department chair at Johns Hopkins School of Medicine in the 1990s, there were serious

discussions about where non-AIDS patients were going to be treated as beds at Johns Hopkins Hospital filled with AIDS patients. But with the support of NIH, the United States developed an understanding of basic biochemistry and virology of the HIVvirus, identified a variety of drug targets and, subsequently, developed drugs that have turned HIV infection from a death sentence into a treatable chronic condition. For some patients, the newest research has achieved a true cures to their HIV infection. Considering continued outbreaks and deaths from HIV/AIDS, the potential to reduce this public health risk in vulnerable communities and internationally is profoundly important.

NIH Funding Priorities Based on Congressional Direction & Scientific Assessment

15. In addition to Congressionally directed funding, the Director of the NIH and each institute and center engages with its advisory council, policy makers, scientific and professional societies, and other public stakeholders to identify agency funding priorities. Congress has directed the NIH to assemble accurate data to assess research priorities including information to evaluate scientific opportunities and public health disease burdens, including progress in reducing health disparities. NIH publicizes the data on the study populations of clinical research funding by its institutes and centers on its website. NIH also considers disease burden in the United States and the potential for return on investment to the United States; rare diseases and conditions; and the biological, social, and other determinants of health contribution to health disparities in identifying research priorities. These priorities are reported to Congress and publicized on its website via the NIH strategic plan.

16. At NIGMS, the institute specifically engaged in scientifically based strategic planning on a five-year basis. While I was NIGMS director, we developed the first formal

NIGMS strategic plan, NIGMS Strategic Plan 2008-2012: Investing in the Future.[1] This plan was developed through extensive interactions with stakeholders from different communities around the country and staff across NIGMS and NIH.

17. Once agency priorities have been identified, each institute and center issues notices of funding opportunities (NOFOs) for specific grant mechanisms, some of which are targeted to specific areas and some are open-ended invitations to investigators to propose problems of interest and specific approaches that fall within the given NIH institute or center's mission.

18. As further described below, when reviewing applications for NIH funding, both the institute and its advisory council explicitly consider whether an application is consistent with its mission and scientific priorities identified in its strategic plan.

Review of External Funding at NIH Based on Scientific Merit and Strategic Plan

19. The NIH receives approximately 50,000 grant applications per year. NIGMS alone awards and manages more than 4,500 grants on average and reviews nearly 1,000 grant applications (in addition to those reviewed by study sections at the NIH's Center for Scientific Review) received in response to NOFOs. As part of the NIH mission to advance biomedical research, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

20. Notices of funding opportunities explicitly incorporate the criteria used to assess scientific and technical merit of each grant application. Criteria can include the scientific significance of the proposed project, including the strength of the scientific premises of the grant;

[1] NAT'L INST. GEN. MEDICAL SCIENCES, INVESTING IN DISCOVERY (2007), https://www.nigms.nih.gov/sites/nigms/files/migrated/NIGMS-strategic-plan-2008-2012.pdf

the investigators' expertise and resources; the potential innovative impact of the proposed research; and whether there is a rigorous and feasible approach to address the aims of the project. Other criteria include justification of the proposed budget and duration in relation to the proposed research. For clinical research, patients need to be protected from research risks including the risk of needing to stop the research and the application also needs to address the appropriateness of the proposed study population.

21. When a scientist submits a grant application through their organization, the NIH assigns the application to a study section at the Center for Scientific Review for peer review or to study sections at a specific NIH institute or center for more scientifically specialized topics. Study sections are composed of 20-30 independent researchers from the scientific community who have the expertise to assess topics such as Basic Mechanisms of Diabetes and Metabolism or Chemical Biology and Probes. There are approximately 250 standing study sections that meet at least three times a year on specified topics. Special emphasis panels or study sections also meet to review applications for more specialized programs or for projects that fall outside an existing study section.

22. The study section meets, reviews, and scores an application for scientific and technical merit. The review is time intensive and done on a mostly voluntary basis. Each reviewer on a study section is assigned between 4-10 applications. Each application has two primary reviewers and an additional reader who present the application for discussion at one-to-two-day meetings. Scores can significantly shift as key features or flaws are noted. Scores from different study sections are normalized so that scores from different study sections can be compared. Fewer than half of applications make it through this part of the process with a significant chance of being selected for funding.

23. Advisory councils from each institute or center then meet and review the grant critiques (called summary statements) with NIH staff to ensure that the first level of peer review appears to have proceeded appropriately and to assess alignment of the application with the institutes' funding priorities. Advisory councils are committees of 10-12 academic scientists and other experts (e.g., patient advocates, economists) who typically serve four-year terms and are appointed by the Secretary of Health and Human Services. Advisory councils provide oversight of the first stage of peer review and make recommendations about applications that should be given higher or lower priority given the state of science in a given institute or center's field, and the mission and extant portfolio of said institute. Advisory councils typically meet three times a year with meetings scheduled years in advance. These meetings align with the normal funding cycles for grant review process.

24. Finally, each institute and center's director make funding decisions with the advice of program officers and senior leaders in the institute or center. Funding decisions are largely based on peer review scores, but also with consideration regarding the existing grant portfolio, a center's publicized priorities, or recommendations of staff. Budgets are adjusted based on peer review, staff recommendations, and the availability of Congressionally appropriated funds. Grants are then awarded to each researcher's institution.

25. Before this year, I have never observed nearly all study sections and advisory councils canceled for a funding cycle. On January 21, the Acting Secretary of Health and Human Services informed NIH that all notices in the Federal Register would need to be approved by a Presidential appointee. This is important because study sections and advisory councils are committees subject to the Federal Advisory Committee Act (FACA), a transparency statute enacted in 1972. My understanding is that this law was intended to prevent the federal

government from receiving advice in secret. Here, it was being used to block normal grant-making processes. Approval of grant applications and peer review is required in order for an application to be eligible for funding.

Continued Funding at NIH Based on Scientific Merit & Performance

26. NIH staff, such as grant management officers and scientific review officers, are also assigned to manage the more than 59,000 grants that NIH manages in a year. In 2023, these grants supported 38,000 principal investigators and more than 300,000 researchers at more than 2,500 institutions across the country.

27. Due to the nature of funding scientifically significant but innovative and sometimes risky nature of biomedical research, investigators have the flexibility to adjust their research efforts depending on ongoing discoveries or other developments in the scientific field. But the NIH's staff still review annual progress reports to assess whether or not the researcher has continued to make progress on the project appropriate for what was in their grant application.

28. NIH program officers and grants management specialists must review these reports and approve a new year of funding through an administrative review without the involvement of study sections and advisory councils. As mentioned above, due to the importance of funding stability in advancing scientific investigation—absent scientific misconduct or other significant events—these funding streams are almost always approved in a timely manner as grants come up for review based on their start date.

Rarity of Grant Terminations

29. The NIH rarely terminates grants. I do not recall any instances of such terminations by NIGMS during my nearly eight years as director. Prior to 2025, I am only aware of two such terminations in subsequent years. One involved an aging investigator who was not

longer able to conduct the research (and who died shortly thereafter) and another involved an investigator fired from his university of sexual harassment involving younger scientists.[2]

30. Otherwise, in instance of concerns about performance of the grant, rather than terminating a grant, the NIH has generally discussed with the grantee or with others at the grantee organization to pursue corrective action prior to making any additional awards.

31. Finally, in instances of scientific misconduct, the NIH still seeks to preserve the results of the research if possible. Scientific misconduct includes, but is not limited to, fabrication of the data and results from a scientific study or plagiarism of another person's processes and results without giving appropriate credit.[3] Under many circumstances, misconduct investigations, conducted by the grantee organization or their designee, identify problematic scientific publications and push for correction or retractions for impacted publications. But in other instances, publications are cleared by the investigation with no evidence of influence on the publication due to the inappropriate behavior.

Funding Disruptions Devastating, Without Alternatives

32. In the long term, if these disruptions in Congressionally directed funding continue, the biomedical enterprise both in public and private institutions is in danger. As an example of how basic research helps to fuel rapid progress in developing new and safer treatments and prevention strategies, the U.S. Food & Drug Administration recently approved a

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[2] *See* Amy Harmon, *Chicago Professor Resigns Amid Sexual Misconduct Investigation*, N.Y.TIMES (Feb. 2, 2016), https://www.nytimes.com/2016/02/03/us/chicago-professor-resigns-amid-sexual-misconduct-investigation.html

[3] Office Res. Integrity, *Definition of Research Misconduct*, DEP'T HEALTH & HUMAN SERVS., https://ori.hhs.gov/definition-research-misconduct (last visited on Apr. 2, 2025).

first-in-class non-opioid medicine for mild to moderate pain (suzetrigine, brandname Journavx).[4] This was based on decades of basic and more applied research in NIH-funded academic and private-sector laboratories. The loss of any of the large amount of information or techniques generated from this research would have made approval of this pain medication impossible. Move over, many of the scientists involved— including those in industry—were trained at the NIH or in academic laboratories supported by the NIH. In the long run, these advancements have the potential both to provide a new alternative to treat post-surgical pain, but also to address the demand side of the opioid public health crisis.

33. There are not alternative sources to replace the NIH's more than $40 billion in biomedical research funding. In 2022, the NIH invested more than 25 more times on grants than the next largest funder, the Wellcome Trust based in the United Kingdom.[5] Combining then the next 25 largest funders of biomedical research would not replace the NIH's annual funding of biomedical research. Moreover, as private or non-US based funders, those funders are unlikely to have the same priorities identified by Congress and by US-based researchers and stakeholders.

Conclusion

34. As an undergraduate, graduate student, and postdoctoral fellow, my training and research were supported through research grants to my research mentors. When I started my independent career, my research projects were funded through a then-new program directed to beginning faculty members. The continuity of Congress and the American people's investment in biomedical research via the NIH has been vital to my career path. The United States has

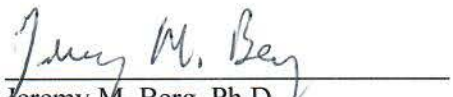
[4] Press Release, FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain (Jan. 30, 2025), https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain

[5] Nisha Gaind, *How the NIH Dominates the World's Health Research*, 639 NATURE 554 (2025), doi: https://doi.org/10.1038/d41586-025-00754-4

similarly invested in the training and research of numerous students, early career scientists, and faculty in every state and territory. It is a shame that these interruptions in NIH funding now endanger the advancements and institutions powered by those individual researchers.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 2nd day of April 2025, in Gibsonia, PA.



Jeremy M. Berg, Ph.D.
Former Director (2003-2011)
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 38

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF RAFAEL JAIME

I, Rafael Jaime, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the President of UAW Local 4811, the labor union representing over 48,000 academic workers across the University of California system. I have personal knowledge of the facts stated below or have obtained them through consultation with our members, stewards, and staff, as well as from institutional correspondence and grievances. If called as a witness, I could and would competently testify to the facts stated here.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Background

3. UAW Local 4811 represents academic workers across the ten campuses and medical centers of the University of California, as well as Lawrence Berkeley National Laboratory. Our members include postdoctoral scholars, graduate student researchers, academic student employees (such as teaching assistants), and other academic researchers. Together, these

workers form the backbone of publicly funded academic research at UC, including research funded by the National Institutes of Health ("NIH").

4. For nearly three decades, UAW 4811 has fought to make UC a better place to work, teach, and conduct research. We bargain for contracts, enforce our members' rights, and organize for dignity in research work and public education.

Reliance on NIH Funding and Harm to Our Members

5. Since late January 2025, we have witnessed mounting disruptions in NIH-funded research across the campuses where our members work. Our members rely heavily on NIH funding streams—either directly, via individual fellowships and training grants (e.g., F31, F32, K99, T32), or indirectly through lab employment supported by faculty-held NIH grants.

6. Delays in funding NIH grants and terminations of grants have had, and continue to have, the following impacts on our membership:

a. *Job Insecurity and Interrupted Appointments*: We have received widespread reports that members' appointments have been shortened, renewal decisions delayed, or start dates rescinded because of uncertainty surrounding NIH funding. Postdocs, academic researchers and graduate student researchers in particular have been told by principal investigators (PIs) that they cannot be reappointed unless or until NIH makes funding determinations that are months overdue. Since March 5 of this year, we have received 17 layoff notices, 2 reductions-in-time, and 6 non-renewals of contracts due to NIH funding cuts and delays. These numbers are sure to increase as the number of cancelled grants increases and awards are further delayed.

b. *Disruption of Research and Academic Progress*: Many of our members report being unable to complete their experiments or thesis research. Some have had to abandon critical data collection due to the unavailability of lab resources. NIH grant uncertainty has caused members to pause ongoing projects, re-scope dissertation topics, and in some cases, consider leaving their programs entirely. At UCSF, a grant to study infectious diseases was suddenly cancelled leaving hundreds of researchers without funding to complete a multi-year study.

c. *Visa and Immigration Risk*: Close to 50% of our postdoctoral and academic researcher, and graduate student membership holds F-1, J-1 or H-1B visas, which require ongoing employment and sponsorship. Multiple members have contacted our union in distress over the prospect of losing visa status due to lapses in funding or expiring contracts. In some cases, union members have sought, with assistance from their union, bridge funding or alternate sponsors to keep from having to leave the country or being deported.

d. *Missed Career Milestones*: Several members planned to apply for K99 or other independent NIH awards this spring but were advised by faculty to delay applications until NIH resumes normal operations. Others missed application windows altogether due to the lack of institutional support for reference letters and compliance review during the funding freeze. We are aware of members who have withdrawn from job searches, declined postdoctoral offers, or may need to delay graduation due to NIH-related instability. In addition, we are aware of members who are seriously exploring opportunities outside the United States as a result.

7. Across the University of California, we are seeing systemic impacts:

   a. Principal Investigators and departments have frozen hiring for NIH-funded postdoc, academic researcher and graduate student positions, or have stated they will imminently need to do this;

   b. NIH-funded labs have been forced to halt experiments and conserve discretionary funds in anticipation of grant denials or terminations, or have stated they will imminently need to do this;

   c. Postdocs, academic researchers and graduate students working on NIH training grants have been left in limbo due to non-renewals;

   d. Our union has fielded an increasing volume of inquiries and grievances regarding shortened appointments, lack of notice, and abrupt changes to work assignments and funding.

8. For example, one of our members, a postdoctoral researcher in infectious diseases, was told by their PI that their appointment could not be renewed after July 7th because the R01 they were funded under was suddenly cancelled. The member is on a J-1 visa and is now at risk of deportation.

9. The member in the above example is just one of over 200 researchers who are being impacted by the cancellation of a single grant at one UC campus.

10. Our members are at the front lines of American biomedical research—developing therapies, conducting basic science, and contributing to public health advancement. Yet their careers are being destabilized by bureaucratic inaction and unexplained political interference.

Irreparable Harm

11. The loss of stability, research continuity, and training momentum is already having lasting effects. Even if NIH resumes normal grant processing and ceases terminating grants tomorrow, the damage done to our members' careers, experiments, immigration status, and trust in the research enterprise is irreversible.

12. Our members represent the future of publicly funded science. The delays are already chilling career interest in postdoctoral research and graduate education, which threatens to create downstream shortages of qualified biomedical researchers and faculty.

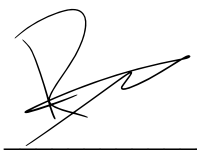
13. Many of the affected members are first-generation scholars or from historically marginalized groups, including those working on NIH-funded disparities research. The disruption has a disproportionate effect on efforts to diversify the biomedical research workforce.

14. The harms fall disproportionately on international scholars, first-generation college graduates, and members of underrepresented communities who cannot weather prolonged uncertainty or self-fund their research careers.

Conclusion

15. The NIH's failure to timely review, approve, or renew grants has caused serious and compounding harm to our members—jeopardizing their work, their livelihoods, and in some cases, their ability to remain in the country. It is undermining the very infrastructure of American biomedical research.

Executed this 2nd day of April 2025 in Los Angeles, CA.



Rafael Jaime
President
UAW Local 4811

EXHIBIT 39

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

EXHIBIT 40

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF RYAN HUTCHINGS, PH.D.

I, Ryan Hutchings, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am employed as a Research Associate II at the California Department of Justice. I make this declaration based on my personal knowledge and in support of Plaintiffs' motion for a preliminary injunction.

2. The Federal Register makes public notices available through a RESTful API ("Federal Register API"), as described at https://www.federalregister.gov/developers/documentation/api/v1. This API provides programmatic access to official notices published by federal agencies, including meeting notices issued by the National Institutes of Health ("NIH").

3. I developed code to collect and analyze Federal Register notices issued by NIH for the period from 1 January 2009 to 12 April 2025. This code (1) systematically identifies NIH meetings related to the review of grant applications, (2) quantifies the cumulative number of

grant-related NIH meetings held each fiscal year noticed in the Federal Register, and (3) visualizes the results of this analysis.

4. Because a single notice posted in the Federal Register may be related to multiple such meetings, and because the formatting of notices varies, my code individually analyzes the full text of each notice (as represented by the XML documents provided by the Federal Register API) and attempts to find and organize relevant information about any meetings it contains.

5. At a high level, the portion of the code related to analyzing the full text of the notices performs the following functions:

a. *Center/Institute Identification*: Using a database of NIH centers and institutes, including full names and abbreviations, compiled from an external reference file, the code attempts to associate API data with the formal NIH center or institute name. However, because there may be variations in how centers and institutes are named across notices (e.g., because of errors), the code matches names using both an exact and an approximate matching procedure.

b. *Multiple Meetings*: The code identifies notices that appear to refer to multiple meetings based on the inclusion of multiple dates, times, locations, agendas, committee names, and/or contact person names and attempts to separate said notices into multiple meetings. The goal of this step is to mitigate against over- or under-counting the number of meetings held each year.

c. *Grant-Related Meeting Detection:* To determine whether a meeting concerns the review of grant applications, the code examines the agenda or purpose section of notices when such information could be successfully identified and analyzed by the code. It searches for indicative phrases such as “grant application,” “review of

applications," and "evaluate grant proposals." This code assumes that meetings containing these specific phrases are related to grant review. NIH meetings that are not related to grant review are excluded from the analysis.

d. *Amendments and Cancellations*: The code identifies amendments and cancellations by detecting keywords in the subject lines or titles of the notices such as "amendment" or "cancellation." I excluded notices identified as amendments and cancellations from the analysis to avoid counting the same meeting multiple times.

e. *Date Identification and Normalization*: The Federal Register API provides the publication date of the notice as well as the scheduled date or dates the noticed meeting. When multiple meetings were noticed, I supplemented the dates with information from the full text of the notice. When the code could not successfully detect or normalize dates from the API data or the full text data, the meeting was excluded from the analysis. This step was necessary to produce the visualizations presented below.

6. This code outputs a structured data file in a R programming language data format containing each meeting's date, institute, committee name, meeting type, agenda, and whether it is an amendment or cancellation, among other information ("the output database"). The output database included 53,237 meetings noticed from 1 January 2009 through 12 April 2025. The output database also identified meetings that could not be interpreted by the code based on the content of the notice for approximately 2,008 meetings. However, I excluded meetings from the output database for several reasons (see above). Exclusions were made in the following order. First, I removed 3,387 scheduled meetings related to amendment and cancellation notices.

Second, I removed 9,985 scheduled meetings that were not deemed grant related. Third, I removed 721 scheduled meetings that did not exactly or approximately match any formal NIH center or institute name. Fourth, I removed 65 scheduled meetings that did not have a date which could be identified or normalized. Fifth, I removed 1,817 meetings that were scheduled to occur before the beginning of Fiscal Year 2010. Finally, I removed 251 meetings that were scheduled to occur between 22 January 2025 and 15 March 2025 based on the assumption provided by counsel that these meetings did not occur as scheduled (see also ¶¶ 9- 10 below). This final exclusion was only made for Fiscal Year 2025, meaning that in all other fiscal years, this analysis assumes that meetings occurred as scheduled.

7. This code allows for systematic, reproducible identification and classification of NIH grant-review meetings from the text published in the Federal Register accessed via the API.

8. According to the output database, between Fiscal Years 2010 and 2024, NIH issued approximately 4 notices of cancelled meetings on average per year. The output database contained 3 such cancellations in Fiscal Year 2025. Amendments were more common than cancellations. The output database contained approximately 98 amendment notices issued by NIH each fiscal year from 2010 through 2024. The output database contained 48 such amendments in Fiscal Year 2025. I can conclude that the number of amendments and cancellations did not occur disproportionately in any of the examined fiscal years, such that their inclusion or exclusion would meaningfully impact the analysis. For this reason, this analysis and the visualization below exclude all amendment and cancellation notices.

9. The output database did not contain any notices for NIH grant-related meetings between 22 January 2025 and 3 March 2025. I was informed by counsel that the NIH adheres to a 15-day statutory notice period, meaning meetings noticed after 3 March 2025 could not occur

before 18 March 2025. Nevertheless, to be conservative my analysis only excludes meeting scheduled to occur between 22 January 2025 and 15 March 2025.

10. The output database contained 251 NIH grant-related meetings noticed prior to 22 January 2025 and scheduled to occur between 22 January 2025 and 15 March 2025. The output database did not contain any cancellation notices regarding these 251 meetings.

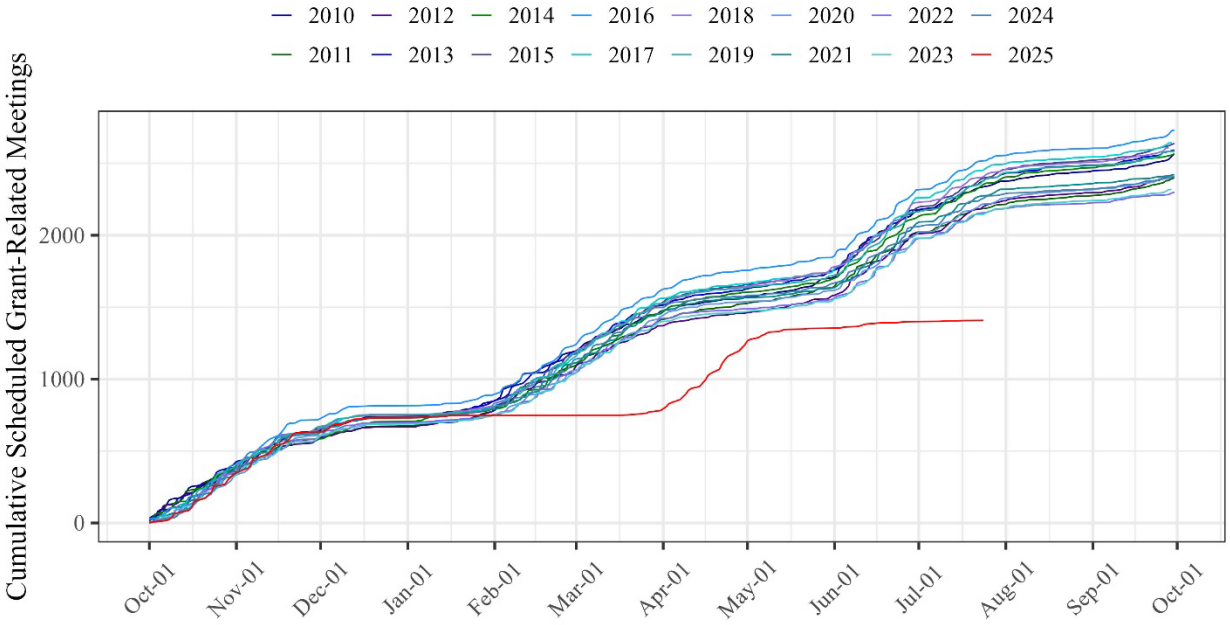
11. The output database contained 935 NIH grant-related meetings scheduled to occur in Fiscal Year 2025 between 1 October 2024 and 12 April 2025 after excluding meetings that were scheduled but ostensibly did not occur between 22 January 2025 and 15 March 2025. During the same period from 1 October to 12 April in each fiscal year between 2010 and 2024, the output database contained between 1,419 and 1,703 scheduled NIH grant-related meetings, with an average of 1,542 scheduled grant related meetings. Based on these figures from the output database, I can conclude that the number of NIH grant-related meetings scheduled from 1 October through 12 April in Fiscal Year 2025 was approximately 61% of the historical Fiscal Year 2010-2024 benchmark after removing scheduled meetings that ostensibly did not occur in Fiscal Year 2025.

12. In addition to the above-mentioned code, I also developed code to visualize the change in the number of scheduled NIH grant-related meetings over time. This visualization code transforms the output database into clear, color-coded graphs where each line represents a different NIH Fiscal Year and shows the cumulative number of grant-related meetings over time. Fiscal Year 2025 is highlighted in red to allow for comparison.

13. Figure 1 visualizes the cumulative number of meetings that were scheduled to occur based on the output database. Figure 1 displays 1 October to 30 September for Fiscal Years 2010-2025, excluding meetings that had been noticed before 22 January 2025 and

scheduled to occur between that date and 15 March 2025, on the assumption that all or nearly all were cancelled. Values in Figure 1 are plotted on the day the meeting was or will be scheduled to occur.

Figure 1: Cumulative Scheduled Grant Related Meetings from 1 October to 30 September Fiscal Years 2010-2025 After Removing Assumed Fiscal Year 2025 Cancellations.



Note: Values are plotted on the day of the scheduled meeting.

14. I believe that Figure 1 shows that the cycle of scheduled meetings occurred consistently in Fiscal Years 2010-2024, but that this cycle was disrupted in Fiscal Year 2025.

Executed this 14 April 2025 in Sacramento, CA.

Ryan J Hutchings

RYAN HUTCHINGS

EXHIBIT 41

BA LITIGATION SERVICES

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In the Matter of:

State of WA, et al.

vs

Trump, et al.

MICHELLE BULLS

April 03, 2025

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STRATEGY • TECHNOLOGY • DESIGN • DEPOSITIONS

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

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

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:

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ALSO PRESENT: Miranda Berge, Esq. - HHS
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I N D E X

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MICHELLE G. BULLS

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P R O C E E D I N G S

- - - - -

(Bulls Deposition Exhibit 1 was premarked.)

Thereupon,

MICHELLE G. BULLS,

was called as a witness by counsel for Plaintiffs, and, having been duly sworn by the Notary Public, was examined and testified as follows:

EXAMINATION

BY MR. McGINTY:

Q Could you state your name and spell your last name for the record, please.

A Sure. Michelle Bulls, B-U-L-L-S.

Q Great. And have you ever been deposed before?

A No.

Q Okay. So just in terms of ground rules, we're here so that I can ask you some questions about what you know about the case. I'll ask you questions and you'll answer them unless you're instructed by counsel not to do so.

Is that fair?

A That's fair.

Q Okay. It's important we make a clear

record, so please wait for me to ask my question and I'll wait for you to answer. Is that fair?

A That's fair.

Q If you don't understand a question, will you tell me?

A Yes.

Q Great. And if you answer a question, I'm going to assume that you understood it.

Is that fair?

A That is fair.

Q This isn't an endurance test. If you need to take a break for any reason, let me know. I'll try to accommodate you as soon as I can. I just ask that you answer any question that's pending before we take a break. Is that fair?

A That's fair.

Q Okay. Now, do you understand that you are testifying under oath today?

A Yes.

Q And what's your understanding of testifying under oath?

A That I need to tell the truth.

Q Okay. And why is it important that you tell the truth when you're under oath?

A Because you need to understand the facts

as I know them and they need to be true.

Q Okay. And you agree that you're going to tell the truth today?

A I do.

Q Okay. Is there any reason that you can't answer my questions truthfully today?

A No.

Q Okay. Has anyone told you not to tell the truth at this deposition?

A No.

Q Okay. Has anyone threatened you or told you that bad things would happen if you told the truth?

A No.

Q Has anyone told you that good things would happen if you didn't tell the truth?

A No.

Q Okay. How did you prepare for this deposition?

A I read through e-mails and just familiarized myself and spoke with counsel.

Q What e-mails did you read through?

A E-mails that I received.

Q Okay. And who did you receive those e-mails from?

A E-mails from my supervisor.

Q Okay. Who is your supervisor?

A My supervisor was Liza Bundesen.

Q Bundesen?

A Mm-hmm.

Q Is that the only person who sent you e-mails that you reviewed?

A Yes.

Q Okay. Did you review any e-mails that you've sent?

A Yes.

Q Okay. What e-mails that you sent did you review?

A I reviewed e-mails that I sent to Chief Grants Management Officers.

Q Okay. And, just, could you tell me what a Chief Grants Management Officer is?

A It's an officer that is in the Funding Institutes and Centers that is authorized to make NIH awards on behalf of NIH and HHS.

Q Okay. And when you sent those e-mails, would they have been sent to all the Chief Grants Management Officers or just to some of them?

A Some of the e-mails were sent to all of them.

Q And some of them were sent to less than all of them?

A Correct.

Q Okay. And so for those that were sent to less than all of them, who were those sent to?

A The -- I don't recall the institutes that they were sent to, I apologize.

Q Do you recall the people?

A I recall one person.

Q Okay. Who is that?

A Maggie Young.

Q Maggie Young?

A Mm-hmm.

Q And Maggie Young is the Chief Grants Management Officer for?

A The Child Health Institute.

Q Okay. Is that NICHD?

A Correct.

Q Okay. So you reviewed e-mails from your supervisor, Liza Bundesen. You reviewed e-mails that you sent to Chief Grants Management Officers.

Did you review any other documents?

A In e-mail form? Yes, I did.

Q Okay. What other -- so you reviewed other documents in e-mail form? Is that what you just

said?

A Yes, I was trying to -- when you said, "other documents," I was trying to understand what you meant.

Q Sure. No, that's fair.

So what other documents in e-mail form did you review?

A I reviewed the -- I don't know what it's called, where you -- where I'm supposed to come and provide documentation, or provide documentation for the -- this session.

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

A For this deposition.

Q I'll go ahead and hand you what has been marked Exhibit 1.

(Bulls Deposition Exhibit 1 was introduced into the record.)

MR. McGINTY: Give a copy to counsel.

(Document tendered to Ms. Andrapalliyal)

BY MR. McGINTY:

Q Is this the document that you were just referring to?

A Yes.

Q Okay. And just for the record, this is the Subpoena Duces Tecum that was served upon you

for today's testimony and a production of documents, right?

A Correct.

Q Okay.

MS. ANDRAPALLIYAL: I just want to, sorry, state for the record we do have a standing objection to the testimony here today. This Subpoena Notice and Deposition Notice were served in accordance with expedited discovery that the Court ordered in connection with its order denying the Court's motion for -- or, the Plaintiff's Motion for Contempt. And that motion concerns a grant that NIH terminated.

That grant has been since reinstated, and so it's our position that those discovery requests -- and I say discovery in general -- has been mooted. That being said, we understood that this deposition is moving forward today, but we just wanted to make that objection for the record.

MR. McGINTY: Okay. I won't respond to that right now, but if we need to follow up, we will.

BY MR. McGINTY:

Q Okay. So you said that you reviewed other documents in e-mail form. And when you answered that question as to what documents in e-mail form

you reviewed, I think you said this Subpoena that I just put in front of you marked as Exhibit 1.

Is that right?

A That's right.

Q Okay. I'm going to get to the Subpoena in a little bit, but are there any other documents, other than the ones you've talked about, e-mails from your supervisor, e-mails that you sent, this Subpoena document, any other documents that you reviewed in preparation for today's deposition?

A No other documents.

Q Okay. And did you talk to anybody in preparation for today's deposition?

A Yes.

Q Okay. Who did you talk to?

A I spoke with the Office of General Counsel and DOJ.

Q Okay. And did you talk to anybody else?

A My husband.

Q Okay. What did you tell your husband?

A I need you to take me.

Q Okay. Anything else?

A No.

Q Okay. You didn't talk to anybody else about today's deposition?

A The counsel.

Q Oh, yeah, yeah. What I meant is, you talked to DOJ, you talked to OGC, Office of General Counsel?

A Yes.

Q And you talked to your husband?

A I talked to my husband. And I alerted my supervisor, my current supervisor, that I had to come to the deposition.

Q Okay. And who is that?

A Jon Lorsch.

Q Jon Lorsch? Can you spell that for me.

A L-O-R-S-C-H.

Q Okay. And did you talk substantively about what your testimony might be today?

A No.

Q Okay. Did he ask any questions?

A No.

Q Okay. Let's turn to the Subpoena that's been marked as Exhibit 1. So you got a copy of this?

A Yes.

Q Okay. And when did you get a copy?

A I'm not sure.

Q All right. If you could turn to page 5 of

Exhibit 1, there's a numbered list titled, "Requests for Production." Do you see that?

A Yes.

Q Did you review that before today?

A Yes.

Q Okay. And what efforts did you make to collect the documents that were asked for here?

A I went through my e-mails and tried to find anything that I could provide.

Q Okay. And did you find e-mails that would match the descriptions in this list?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion.

BY MR. McGINTY:

Q You can answer.

(Witness reviews document)

THE WITNESS: Yes.

BY MR. McGINTY:

Q Okay. What e-mails were those?

A The e-mail that I sent to -- oh. Well, the e-mails that I received related to the termination.

Q Mm-hmm.

A The e-mails that I sent to the Chief Grants Management Officers related to the

termination, the letter of termination, and a response -- responses to requests for me to make the termination.

Q Okay. When you say, "the termination," you're talking about termination of a grant where Dr. Kym Ahrens was the principal supervisor at Seattle Children's Hospital. Is that what you're talking about?

A I'm talking about that includes, yes, the grant.

Q Okay. And anything else?

A I don't recall.

Q Okay. Did you only look for e-mails, or did you look for any other kinds of documents?

A E-mails.

Q Only e-mails?

A (Nodding head)

Q Okay. Is that because no other documents exist or because you didn't look?

A The e-mails had other documents attached.

Q Okay. So let's just go through, I guess. Let's start with Number 1. This request calls for all drafts in your possession, custody, or control of the following documents included as an exhibit to the declaration of Kym Ahrens and William McGinty.

Did you get copies of those documents so you could verify that you had -- to see if you had other copies of those versions of documents?

A No.

Q You didn't get copies of those?

A I don't recall.

Q Okay. So Number 2 asks for all drafts in your possession, custody, or control of the document titled "Staff Guidance - Award Assessments for Alignment with Agency Priorities - March 2025."

Do you know what document that's talking about, Staff Guidance - Award Assessments for Alignment with Agency Priorities?

A Yes.

Q Okay. And do you have a copy of that?

A Yes.

Q Okay. And did you give that to counsel?

A Yes.

Q Okay. How many versions of that exist?

A At the time I gave it to counsel or today?

Q Today.

A Probably two or three.

Q Two or three versions of that exist?

A Maybe -- yeah, I'll say three.

Q Three? Three that exist.

And how many versions existed when you gave it to counsel?

MS. ANDRAPALLIYAL: Objection. That's privileged information.

I'm going to instruct you not to answer.

BY MR. McGINTY:

Q Okay. When is the most recent version of that document dated?

MS. ANDRAPALLIYAL: Objection. To the extent it's calling for draft information, privileged, I'm going to instruct you not to answer.

MR. McGINTY: She just testified that there's three versions of the document. She testified there's three versions of the document.

BY MR. McGINTY:

Q Are any of those -- were any of those used to implement NIH policy?

A They were used to provide guidance. And there's the one document, that was used to provide guidance. The rest of them have been draft versions trying to update the guidance, so.

Q Okay. Were they distributed to NIH staff?

MS. ANDRAPALLIYAL: Objection. To the extent we're talking about drafts, I'm going to instruct you not to answer on privileged grounds.

MR. McGINTY: The question doesn't call for the content of any document. You substantiate your objection on privilege?

MS. ANDRAPALLIYAL: Well, the deliberative process privilege doesn't just cover the contents of the document, but it covers the communications that go into the deliberative process. And so timing and who received what, that's part of the process that should be protected.

BY MR. McGINTY:

Q So it's your testimony today that only one version of that document was ever used by NIH staff for purposes of implementing NIH policy?

A I don't know if they used it. It was provided to them to provide guidance to them on how to implement or assess their portfolios. So --

Q Okay.

A -- I don't know.

Q It was given to them so that they could assess their portfolios in conformance with the guidance?

A Yes.

Q So it was used by them to assess their portfolios. Is that right?

A That is correct.

Q Okay.

MR. McGINTY: Do you maintain your privilege objection, Counsel?

MS. ANDRAPALLIYAL: I maintain the privilege objection as to drafts. I don't maintain it as to the final version.

MR. McGINTY: Okay.

BY MR. McGINTY:

Q How many versions of that document were used to, for staff to assess their portfolios?

A Can you repeat that question.

Q Yeah. I guess I'm trying to understand is how many versions of that document were actually used for the purposes of NIH doing its work, including assessment of portfolios? Was it all three, was it only two, was it only one?

A So they only received instructions to use the first version. The second and third versions are versions that we worked on together as they had questions and I answered them through the Staff Guidance.

Q Okay. But did they use those versions to assess their portfolios?

A I don't know if they used those versions to assess their portfolios.

Q Okay. Were they instructed to?

A They were instructed to -- they were instructed to use the Staff Guidance to assist them in addressing, because they had questions, to assist them in addressing their questions and concerns. So if that is considered.

Q If that is considered?

A If that's considered giving, telling them, or using it as Staff Guidance to assess their portfolio, then yes.

Q Okay. So, and how many -- so it sounds like, if I'm understanding this right, and tell me if I'm wrong, it sounds like there was a version of the document that was sent out to staff, they were instructed to use this to assess their portfolios, if they had questions, the document changed in response to their questions. They continued to use the updated version to assess their portfolios.

Am I right so far?

A They were uncomfortable with using all of the new, you know, the additional pieces because we were still awaiting additional guidance. So they had questions about the original, we addressed those questions. And staff were still a little hesitant about using -- some staff were hesitant about using

it, but they wanted to have it so that when they were able to use it, they could.

Q Okay. So some staff were using it and some staff didn't want to. Am I understanding that right?

A Yes.

Q Okay. And right now we're talking about the second version?

A Yes.

Q Okay. And then there were continued questions about this, and so you got more questions about it, and a third version was created. Is that right?

A Yes, yes.

Q Okay. And this third version, was that used by staff to assess their portfolios?

A I don't know.

Q You don't know. Okay. Why not?

A Because we were still -- they were still waiting for me to issue the final guidance.

Q And that has yet to be done?

A And that has yet to be done.

Q Okay. So the first one has been used to assess portfolios. The second one was used by some people to assess portfolios. The third one you

don't know. And there's a final that's forthcoming?

A Yes. It's been an evolving document. And so, like I said, some of them were -- some of the IC staff were comfortable in using the document, some of the staff were, decided that they were going to stop and wait for the final document. So it's been a bit of back and forth.

Q Okay. And "IC," Institute/Centers?

A Institutes and Centers.

Q Thank you.

A You're welcome.

Q Let's see. And then item Number 3 asks for all communications made to or by you related to documents identified in Requests for Production 1 and 2.

It sounds like there was lots of communications to and by you about all of these documents. Is that right?

A Yes.

Q Okay. And did you collect all of those communications?

A I believe I did.

Q Okay. And you gave them to counsel?

A I believe I did.

Q Okay. Let's see. And then all documents

in your possession, custody, or control, including communications made to or by you, related to termination of NIH Grant No. -- and then there's a grant number there -- 5R21HD107311. That's the document we were just talking about with Kym Ahrens as the principal investigator. Is that right?

A I do recognize the grant number, yes.

Q Okay. And it sounds like there's all kinds of documents that would be responsive to that one, too?

A Correct.

Q Okay. And you gave those to counsel?

A I --

MS. ANDRAPALLIYAL: Objection. Just a standing objection here to the extent that we're going through all these requests that are calling for a legal conclusion where you're asking her whether she has collected all of the documents responsive to these requests.

MR. McGINTY: Are you instructing the witness not to answer?

MS. ANDRAPALLIYAL: No.

BY MR. McGINTY:

Q Could you repeat your last answer for me.

A Can you repeat the question.

Q Yes. I think I just asked you if you gave them to counsel.

A I believe so.

Q Okay. So next one asks for all documents in your possession, custody, or control related to NIH's claims that 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.

Did you look for documents related to that request?

A Yes.

Q Did you find any?

A It was in the termination letter. That was the language in the termination letter that was provided to me.

Q Okay. Anything else?

A No.

Q Okay. Number 6 asks for all documents in your possession, custody, or control related to NIH's claim that it is the policy of NIH not to prioritize these research programs. Do you see that?

A Yes.

Q And did you search for documents like that?

A I provided the documents that likely had this in it, but I was not searching for this specific document, if that makes sense.

Q Okay. You were looking for documents that had that quoted language?

A Not the quoted language. I looked for documents that surrounded the termination, and if the termination was based on this, it had that in it. I wasn't looking specifically for this, if that makes sense. I gave what I had and what I received, and I -- that's what I gave.

Q Okay. I guess my question is:

What this is asking for is documents that's related to the claim that it is the policy of NIH not to prioritize these research programs, so did you look for any documents about NIH policy?

A No, I looked for documents related to the termination.

Q Okay. Did you look for any documents related to the policy that animated the termination?

A No, I looked for the documents, the letter that terminated the grant.

Q Okay. Thank you.

So moving on to Number 7. This one asks for all documents in your possession, custody, or control related to NIH's claims that this award related to transgender issue no longer effectuates agency priorities.

So did you look for any documents about NIH priorities in response to this question?

A I looked for the termination documents that may have included that language, but I did not look for that language.

Q Okay. You didn't look for any documents about whether or not it is the policy, or, excuse me, the priority of NIH to fund studies and research related to transgender issues?

A No, I provided the documents that was provided to me that may have included that. I did not search for that.

Q Okay. The next one asks for all documents in your possession, custody, or control that include descriptions of policies, procedures, or guidance regarding termination of NIH grants dated between January 20, 2025 and March 6, 2025. Do you see that?

A Mm-hmm.

Q Did you look for those kinds of documents?

A Yes, I provided all of the documents that, regarding the termination.

Q Okay. And would this have included the document that we were just talking about a minute ago, the Staff Guidance Award Assessments? Would it have included that one?

A Yes.

Q Okay. Are there any other documents about agency priorities or policies that are dated in that range having to do with grant termination?

A No, not that I recall.

Q Okay. The next one asks for all documents in your possession, custody, or control including communications, policy statements, or guidance documents related to or referencing two Executive Orders. Do you see that there?

A Yes.

Q And did you search for those documents?

A I provided the documents that led up to the termination. That's all I provided.

Q Okay. In response to this request specifically?

A In response to the request for me to provide all documentation that led up to, all the

way through the termination. That's what I provided.

Q Okay. How about documents that relate to or reference these two Executive Orders, did you search for that?

A If it was a part of the termination package communication, I did provide it. But I don't know that I searched for the Executive -- like I didn't provide the Executive Order, I don't believe.

Q Okay. So you searched for documents that would have related to the termination we've been talking about, but not necessarily anything else?

A Correct.

Q Okay. Did you search for any documents or any communications between you and any person affiliated with the Department of Government Efficiency?

A I provided all the e-mails, all of the communications, and if that was a part of it, that is part of that package. I didn't look for any communications with Department of Government Efficiency.

Q Okay. Were there such communications?

A There was no communication between, that I

can, that I know of, directly between me and anyone in the Department of Government Efficiency. They may have been copied on the e-mail, but not with me.

Q Okay. Sitting here today, can you recollect any e-mails that they were copied on?

A Yes, one.

Q Okay. Can you describe that e-mail for me?

A I believe that was the e-mail that included a list of grants to be terminated.

Q Okay. So you got an e-mail. Was it from someone at the Department of Government Efficiency?

A No.

Q No. They were copied on one. Who was sending that e-mail?

A The e-mail that I received was from, between me and my supervisor, and there was a string below it. So I wasn't directly on the e-mail with that individual, it was forwarded to me with a list of the terminations.

Q I see. And who was your supervisor at the time?

A Liza Bundesen.

Q That was Liza Bundesen?

A Yeah.

Q And she was given a list of terminations?
A Correct.
Q And that list came from someone at the Department of Government Efficiency?
A That list came from Rachel Riley.
Q Okay.
A And her address was from HHS Office of the Secretary.
Q Thank you. And the Department of Government Efficiency was -- how were they involved in that e-mail?
A Copied.
Q They were cc'd?
A I believe.
Q Okay. So Rachel Riley at HHS sent it to Liza Bundesen, who sent it to you. Is that right?
A Yes.
Q Okay. Can you remember anybody else who was included on that e-mail?
A Not that particular e-mail. Because one of the e-mails came from Dr. Memoli, so those were two separate strings, but both termination e-mails.
Q Oh, okay. So there's another set of terminations. Am I understanding that right?
A It was the same -- yes, yes.

Q Okay. And that one came from Dr. Memoli?
A Yes.
Q But that was -- did it come from the same person at HHS?
A Yes, it came from the same person at HHS to Dr. Memoli that was forwarded to Liza.
Q I see. And who is the person in the Department of Government Efficiency who was copied?
A I believe his name was Brad.
Q Brad. Don't remember the last name?
A I don't.
Q Okay, fine. Okay.
So it sounds like there's at least two e-mails that copied someone at the Department of Government Efficiency. One was forwarded to you by Dr. Bundesen, one was forwarded to you by Dr. Memoli. Are there any others?
A Dr. Memoli didn't forward the e-mail directly to me.
Q Oh.
A He forwarded it to Liza Bundesen, who forwarded it to me.
Q I see. Thank you for that clarification.
A You are welcome.
Q Are there any others?

A No.

Q Okay. Just the two?

A (Nodding head)

Q Okay.

A Yes.

Q Thank you so much. I did not ask you to verbally answer the questions, and I should have done so, so thank you so much for remembering to do that.

A You're welcome.

Q We also asked for a copy of your CV and your resume. Did you give that to counsel?

A Yes.

MR. McGINTY: Counsel, do you have any of those documents to provide today?

MS. ANDRAPALLIYAL: Yes. I believe we've provided you a copy of Ms. Bulls' CV.

(Document tendered to Mr. McGinty)

MR. McGINTY: Thank you. Okay. Let's go ahead and mark this Exhibit 2.

(Bulls Deposition Exhibit 2 was marked for identification.)

MR. McGINTY: Counsel, would it be possible to get a second copy of this?

MR. BOMBARD: For the witness?

MR. McGINTY: I was going to hand the witness the marked copy, and I would like to be able to follow along, if possible.

MR. BOMBARD: Oh.

(Document tendered to Mr. McGinty)

MR. McGINTY: Thank you.

BY MR. McGINTY:

Q Okay. I just handed you what has been marked as Exhibit 2. Do you recognize this document?

A Yes.

Q And what is it?

A My resume.

Q Okay. Feel free to reference this. I'm just going to ask you to go through your job experience and education history since the time you were 18, if that's possible. And to the extent you want to reference what's on the CV and point things out to me, I'd appreciate it.

A Starting forward or backward?

Q Starting forward, please. Let's start, let's go chronological order from the time you were 18.

A From the time I was 18, graduated, some community college, cosmetology school, cosmetology

license. Joined the government in a Pathways Program. Worked in the government from, I guess, 1989 -- I can't recall, but maybe, yeah -- 1989 through now.

I worked through Grants Management Clerk, Grants Management Specialist, Grants Management, Officer at NIH. Went into Policy within the Office of Policy for Extramural Research Administration as an analyst. Left NIH and went to the Indian Health Service to head up their policy office.

Left the Indian Health Service to go to HHS Office of Grants to head up the policy office for HHS. And came back to NIH as the Deputy Director of the Office of Policy for Extramural Research Administration, and then ultimately was appointed as the Director.

Q Okay. So you started -- if I understand you correctly, you started with the government through a Pathways Program in 1989. And then you became a Grant Management Clerk in NIH; is that right?

A In the National Heart, Lung, and Blood Institute.

Q Okay. And when was that?

A I don't recall.

Q Okay. Sometime early '90s?
A Yes, around -- well, I started as a Grants Clerk --
Q Oh, I see.
A -- at '89.
Q So that would be the '89. Okay. And then you became a Specialist?
A A Grants Management Specialist.
Q Grants Management Specialist. Approximately when?
A Early '90s.
Q Early '90s. And then Grants Management Officer sometime --
A Mid '90s.
Q Mid '90s sometime?
A Late '90s, yes.
Q Okay. And then you started as a Policy Analyst in OPERA?
A Correct.
Q What were your job duties when you were the Policy Analyst in OPERA?
A I worked in the Division of Grants Policy representing NIH on federal-wide working groups for Grants Administration. I worked on the Grants Policy Statement, the NIH Grants Policy Statement.

Reviewed and analyzed policies and the regulations and provided guidance to the Institutes and Centers.

Q And approximately when was this that you were an OPERA Policy Analyst?

A 2001 to, like, 2004 or '5.

Q Okay. And then approximately then you moved to, you said, the Indian Health Service?

A Correct.

Q And you were -- you said you headed up their Grants Office. Did I understand that right?

A Their grants policy functions.

Q So what were you doing there?

A Implementing, helping to identify policies under HHS that directly conflicted with the Indian -- I don't even know. I'm -- Title 25 where, you know, it was the Indian Determination, Self-Determination Act identified how to implement grant administration functions within the department that would not disrupt the tribal programs, provided technical assistance on how to maintain compliance to the tribes with grant regulations and grant policies.

Represented Indian Health Service through the department on working with, you know, the Tribal Affairs Office, just trying to make sure that we

acknowledged the rights of the tribes and making certain that we provided clear and concise tribal consultation guidance and that kind of thing.

Q Okay. And how long were you there?

A I was there for five years maybe?

Q Okay. And then you moved to the HHS Office of Grants Policy. Did I understand that right?

A Yes. The HHS Office of Grants, and I was in the -- I was the director for the Policy Division.

Q Okay. And so if I'm tracking right, we're off to the mid 2000s now?

A I don't know where we are.

(Whereupon, laughter)

BY MR. McGINTY:

Q Well, when did you move to the HHS Office of Grants Policy from the Indian Health Service?

A I moved there, I want to say, 2009.

Q 2009. Okay. And what were you doing when you moved to the HHS Office of Grants Policy?

A Providing grants administration guidance for all of the departments under HHS.

Q Okay. That's a lot of departments.

A Yes, Ops is, yeah, Operations Division.

Q So what would that entail?

A Meeting with the operating divisions, talking to them about, you know, they had questions about various grants, HHS policy -- departmental-wide policies. And I would answer the questions, help them implement the policies, have meetings to go over guidance.

Q Okay. And you started there around 2009. How long were you there?

A Probably about two and a half, almost three years.

Q Two and a half years. And then you became the -- did I understand, from there you became the Deputy Director of OPERA Grants Management. Is that right, or am I saying that wrong?

A OPERA. No, just OPERA.

Q OPERA. Just OPERA. Okay. Great.

So Deputy Director of OPERA around 2011?

A Yes.

Q Okay. And when were you appointed the Director?

A I believe it was 2012.

Q 2012. Okay. So let's talk about your role as the Director of OPERA. What are your duties in that role?

A To provide -- so I have Compliance -- no -- oversee Compliance for NIH policies. Oversee the grants administration functions. Provide oversight to the Institutes and Centers on grants administration. Oversee the Federal Financial Reporting Center where all of the financials are submitted and analyzed.

And I oversee all of the closeout functions for, administrative and financial, for NIH. Administrative compliance, foreign interference, and research misconduct compliance and that kind of thing.

Q Okay. When you say "oversee," what does that mean?

A Provide oversight, like, provide the HHS-wide central level direction and then provide that to the Institutes and Centers for them to implement within their Institutes and Centers, and provide them guidance as needed on implementation. Help them with compliance functions when there's noncompliance.

Work with them on different administrative matters that come up either through the administrative business effects of the grants when recipients are noncompliant, or help them develop

corrective action plans for recipients when they're not compliant. And, also, oversee how they are implementing, "they" meaning the Institutions and Centers are implementing our guidance, going and looking at their compliance -- using a compliance model to test to see whether or not they're, you know, following the guidance that we provide, and when they don't, providing them with updates on how they need to manage. Meeting with them on a consistent basis twice a month to discuss policy and compliance issues and to obtain guidance from them on better ways that we can manage NIH grants.

Q Okay. So you meet with -- who do you meet with twice a month?

A I meet with the Institutes and Centers, the -- so I service the Agency Chief Grants Management Officer. And then we have the Institutes and Centers Chief Grants Management Officers that actually issue the awards and oversee the fiscal management of the awards.

Q Okay. And so it's the two times meeting with the Chief Grant Management Officers. Is that right?

A Twice, twice a month.

Q Twice a month. And you talk about,

basically, all of the things that you just went over?

A Correct.

Q Okay. And in issuing the guidance that you just talked about, when you issue that guidance, is that different or the same as the Staff Guidance that we were just talking about a minute ago on Exhibit 1?

A It's the same in that we communicate about the guidance and they get to ask questions. It's different because typically we talk about things that we all are working on, and in the grants management arena, and not this kind of thing. So, yes, the guidance is provided, we talk about it, so that's is the same.

Q Okay. And it's different insofar as -- how is it different? I guess I didn't quite understand.

A It's different because we're typically clear on what we are supposed to be doing with grants administration. And then this particular situation we were just talking about, you know, how do we manage, how do we identify categories and make sure that we are very clear in providing that, those next steps. We want everyone to do things

consistently.

And sometimes with other guidance, institutes have different practices and procedures. So we give the guidance and allow them to go on and do what they do within their individual ICs as long as it matches their processes. In this, it was a very intentional discussion of we all should do it the same way.

Q And when you say, "in this," you mean the Staff Guidance --

A The Staff Guidance, correct.

Q -- that we were talking about on Exhibit 1?

A Yes.

Q Okay. One of the divisions within OPERA is the Division of Grants Policy. Is that right?

A Correct.

Q What's that division, what does that do?

A Implements the NIH Grants Policy Statement, implements the Grants Administration Manuals, answer policy questions, work with programs to make sure that the program policies are enter -- that the Grants Administration regulations govern the program policies.

Q Okay. And if I understood your previous

description, you were a policy analyst. Were you in the Division of Grants Policy?

A I was.

Q Okay. And with your current role, what's your role to that division?

A I supervise the division Director.

Q Okay. What's your role with respect to grant termination, just generally speaking?

A I, generally speaking, with noncompliance I work with the Institutes and Centers to help them determine how to develop corrective actions and help gain compliance with the recipient. I -- and then for other areas, I work with the institutes to complete bilateral terminations, but I don't terminate, typically.

Q So you're saying there's two kinds of terminations. Generally speaking, there's a noncompliance termination, there's a bilateral termination?

A Correct.

Q Could you describe the difference between those two?

A Yes. A bilateral termination is when we work with the recipient and realize that it's in the best interest for the project to be terminated

because we can't come -- can't identify a new principal investigator or whatever the case may be. That's just one example.

And noncompliance terminations, though there have -- they are where the recipient is unilateral, right, that we, NIH, cannot identify or cannot come up with a corrective action plan to help move the project along, and so the decision of the agency would be to terminate.

Q Are you generally involved in noncompliance terminations?

A I'm generally involved in noncompliance discussions, yes.

Q So if a noncompliance termination were to happen, you would probably know about it?

A Correct.

Q Okay. Prior to when President Trump was inaugurated, in the time that you were Deputy Director or Director at OPERA, how many noncompliant terminations were there?

A So deputy director, I don't recall. As the director, maybe one or two. It doesn't happen often.

Q Okay. And, help me. I think you've been director for quite a while. I think you said since

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.

MR. McGINTY: Mark this Exhibit 3, please.

(Bulls Deposition Exhibit 3 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 3.

MR. McGINTY: Counsel.

(Document tendered to Ms. Andrapalliyal)

BY MR. McGINTY:

Q I'm sorry, just one more follow-up question about the terminations that were provided to you.

My understanding is there was an e-mail from Rachel Riley and on which someone named Brad from DOGE was copied on that e-mail, and that applied to the termination for Dr. Ahrens, right?

A I don't recall if that's the same e-mail.

Q Okay. So we'd have to take a look at that e-mail to know?

A Yes.

Q Okay. Do you recognize what I've just handed you as Exhibit 3?

A Yes.

Q And what is this?

A The Executive Order.

Q Which one?

A 14168, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government.

Q Okay. When did you first become aware of this Executive Order?

A I believe the date that it came, that it was issued.

Q Okay. So on January 20th, 2025?

A Yes.

Q Okay. Have you talked with anyone about this document?

A Talked with the Department of Office of Grants.

Q And what did you tell them?

A I didn't tell them anything.

Q Okay. So you talked with the Department of Office of Grants. Is that a department within NIH?

A No, HHS.

Q That's a department within HHS. Okay.

And so, who at the Department of -- excuse me. You'll have to tell me that department name again.

A Department of Grants.

Q Department of Grants. Who at the Department of Grants were you talking to about this Executive Order?

A The leadership there.

Q And who is that?

A The Deputy Assistant Secretary for Grants Dale Bell.

Q Did you say Dale Bell?

A Bell.

Q B-E-L-L?

A Yes.

Q And anyone else?

A And the various operating divisions that were there to ask, you know, just to hear the conversation to -- it was a meeting just to talk about the fact that the Executive Orders had come out and that they would provide guidance as they could.

Q When was that meeting?

A I don't recall.

Q Was it in the week after the Executive Order came out?

A It may have been -- I don't recall. It was definitely not long after it came out, so it might have been a week or two. I don't recall. I

don't want to...

Q Go ahead.

A I don't want to make up a date.

Q Sure, yes. Late January, early February?

A February, probably, late January or February, probably.

Q Okay. And what was said at that meeting?

A That they -- that there were Executive Orders that had come out, recognizing that the operating divisions wanted to obtain guidance and that they would give us guidance as soon as they could. That was the first discussion.

Q Okay. And they didn't tell you to do anything with respect to the Executive Order at that time?

A No.

Q Who else was at that meeting? You said Dale Bell and all the operating divisions. Who is that?

A The Agency Chief Grants Management Officers.

Q Is see. From all of HHS?

A From all of HHS.

Q Okay. And were there any subsequent meetings?

A Yes.

Q Okay. With -- we're talking about with HHS and Dale Bell?

A The same group.

Q Okay. And when was the next one?

A Probably at two or -- two weeks after the first one.

Q So maybe mid February sometime?

A Maybe. Might -- maybe before. I'm not sure. It was shortly after.

Q Okay. What happened at the second meeting?

A We were provided a document -- we asked questions. We asked for guidance on, like, a -- I don't want to say it's frequently-asked questions, but it was really to give us information on how we should address the Executive Orders, because we needed to know how, what we needed to do with them, and so they provided guidance on that.

Q And what was the guidance they provided?

A We were asking whether or not -- because by the time we met the second time, I think the TROs had come out, and so they were going to tell us whether, you know, what we needed to do with those.

Q So was this a meeting about this Executive

Order in particular that's been marked as Exhibit 3, or was it all these Executive Orders?

A All of the Executive Orders.

Q Okay. Was this Executive Order marked as Exhibit 3 specifically discussed?

A No.

Q Okay. And so you said it was Dale Bell at HHS, all the Operating Directors, Chief Grants Management Officers. Anybody else at that meeting?

A Yes, we had Office of General Counsel.

Q Okay. Anyone from the Department of Government Efficiency?

A Not that I know of. I don't know.

Q How was the meeting held?

A Umm.

Q Was it on Zoom?

A Yes.

Q It was on Zoom?

A Teams, yes.

Q It was on Teams. Do you know if there were notes or a transcript made of the meeting?

A I don't know.

MS. ANDRAPALLIYAL: Objection. You know, OGC was present at this meeting so the contents of this meeting are protected under the attorney-client

privilege, and so I'm going to instruct Ms. Bulls not to answer.

BY MR. McGINTY:

Q Did anyone ask for client advice at the meeting, attorney-client advice?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion.

BY MR. McGINTY:

Q You can answer.

A Can you repeat the question.

Q Sure. Did anyone ask for legal advice at the meeting?

A Yes.

Q Okay. Asking -- did you get any direction from Dale Bell about how to implement an Executive Order that did not constitute a request or the provision of the request?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion.

BY MR. McGINTY:

Q You can answer.

A I don't know that I understand the question.

Q Okay. So you had two meetings with Dale Bell. At the second time you had the meeting,

the temporary restraining orders had come out, at least as to some of the Executive Orders.

Do you know if at that time the temporary restraining orders as to this particular Executive Order had come out?

A I don't recall, because we didn't talk about the details of all of the Executive Orders. What we talked about was we were wanting to know if we could fund grants.

Q I see. What was the answer to that question?

MS. ANDRAPALLIYAL: Objection. This conversation was attorney-client privileged. I'm going to instruct Ms. Bulls not to answer.

BY MR. McGINTY:

Q After the meeting, did you stop funding grants?

A No.

Q Do you have any more meetings with Dale Bell?

A Yes.

Q Okay.

A With the group, yes.

Q What was the next one?

A Probably at our chief GMO Council which is

a, you know, a meeting that we always have where we were just -- yeah. That was the third meeting.

Q Okay. And was it about the same topic, how to implement --

A We did discuss this.

Q Okay.

A Not this exhibit, but the -- we discussed the responses that we received for our questions -- from our questions during the previous meeting.

Q Okay. And your questions were: Could you fund grants?

MS. ANDRAPALLIYAL: Objection. Because this is an attorney-client communication, it's privileged. I'm going to instruct Ms. Bulls not to answer insofar as it was an attorney-client conversation or communication.

MR. McGINTY: If I understand the objection correctly, you're only objecting insofar as it was an attorney-client privileged communication.

MS. ANDRAPALLIYAL: Correct.

MR. McGINTY: Do you want to have --

Can we go off the record for a second.

(Discussion off record)

(Recess taken - 10:07 to 10:20 a.m.)

(The record was read aloud as follows:
"QUESTION: Did anyone ask for client advice at the meeting, attorney-client advice?
"MS. ANDRAPALLIYA: Objection, calls for a legal conclusion.
"QUESTION: You can answer.
"THE WITNESS: Can you repeat the question.
"QUESTION: Sure. Did anyone ask for legal advice at the meeting?
"THE WITNESS: Yes.
"QUESTION: Did you get any direction from Dale Bell about how to implement the Executive Order that did not constitute a request or the provision of the request?"
MS. ANDRAPALLIYAL: Thank you.
So I do want to maintain our objections on attorney-client privilege here.
MR. McGINTY: Okay.
BY MR. McGINTY:
Q Before the break, we were talking about these meetings with Dale Bell and I asked you if there's any part of that meeting that you can testify about, because counsel's objection and

instruction not to answer was an instruction not to answer to the extent that attorney-client privileged communications would have been implicated. You've now had an opportunity to talk to your lawyer about that --

A Correct.

Q -- sorry, we spoke over each other.

Is that right?

A Correct.

Q Okay. Is there any part of that meeting that you can testify about today?

MS. ANDRAPALLIYAL: Objection. So objection on the basis of attorney-client privilege, but a separate objection on the basis of deliberative process privilege to the extent that there were deliberative communications at this meeting.

THE WITNESS: Dale Bell coordinated the meeting, but the meeting was specifically to obtain legal guidance on what we could do as agencies under the TROs. So he actually coordinated the meeting, but the meeting was definitely about obtaining legal guidance. That was the sole purpose of the meeting.

BY MR. McGINTY:

Q Okay. We're talking about the second

meeting now?

A We're talking about the second meeting, yes.

Q Okay. Because at that time the TROs had come out --

A Right.

Q -- as to some of the Executive Orders but not necessarily all of them. Is that right?

A That's right.

Q Okay. Was there any other meetings coordinated by Dale Bell?

A The third meeting which he coordinates often which as the Chief Grants Management Officer counsel meeting.

Q Okay.

A Yeah.

Q And what was that meeting about?

A That meeting was about other, you know, Grants Management matters. Additional questions did come up about we wanted additional information and guidance from OGC.

Q Okay. Was any direction or instruction from Dale given to you about this Exhibit 3?

MS. ANDRAPALLIYAL: Objection to the extent that it calls for the provision of

deliberative information that's protected on the deliberative process privilege.

BY MR. McGINTY:

Q Do you understand the objection?

A Yes.

Q Okay. Is there anything you can tell me about that meeting, about any instruction you were given about Executive Order 14168, Exhibit 3?

A The meeting was not about this particular Executive Order. It was about all of the Executive Orders and whether we could continue to, you know, move forward with -- yeah, it wasn't about this. It was about all of them.

Q Okay. My question was: Were you given any instruction about how to implement this particular Executive Order?

A The answer is no.

Q Okay. Were there any of these meetings with Dale Bell where you were given specific instruction about how to implement the Executive Order marked as Exhibit 3?

MS. ANDRAPALLIYAL: Objection to the extent that it calls for deliberative information to be produced, especially about practices that haven't been put into action yet.

THE WITNESS: There were discussions, but no -- Dale did not provide final guidance. It was just us talking about additional questions that we had with regard to the Executive Orders. He did not provide final guidance.

BY MR. McGINTY:

Q Okay. How many of these meetings with Dale Bell did you have about the Executive Orders, about?

A Three.

Q Just three?

A And the -- meaning the last meeting included the Executive Orders because the Chief Grants Management Officer still had questions, but the meeting was a broader meeting. The second meeting was a meeting that he actually coordinated specifically.

Q I see. It sounds like these meetings with Dale Bell happened in a recurring way?

A Correct. The meetings -- the Chief Grants Management counsel meetings happened in a recurring way, not meeting about Executive Orders.

Q Got it. How often did the recurring meetings happen?

A They should be happening once a month.

Q Do they happen once a month?

A We try to have them once a month.

Q Okay. Sometimes they get canceled or postponed?

A Correct.

Q Okay. I believe the question that prompted the question of these meetings was just who have you communicated with about this document, and specifically -- I guess I'll clarify that.

Who have you communicated with at NIH about this document for the purposes of NIH policy and procedure?

A I haven't communicated about this document. I've communicated about just overarching funding and the Executive Orders.

Q Okay. Including this document?

A Yes.

Q Okay. And who have you communicated with about that?

A The Chief Grants Management Officers.

Q Okay. And what have you told them?

MS. ANDRAPALLIYAL: Objection insofar as it calls for privileged deliberative information about action that hasn't been finalized yet.

THE WITNESS: We, as we talked earlier, we

are -- I'm answering -- I'm trying to establish the process by which they can continue. So there's been no final guidance. We've been talking about the Executive Orders.

BY MR. McGINTY:

Q Okay. Can you turn to page -- this is from the Federal Register, so I guess it would be page 8616, and look at Section 3(e).

Do you see that?

A Yes.

Q And it says, the last sentence of Section 3(e):

"Agencies shall take all necessary steps, as permitted by law, to end the Federal funding of gender ideology."

Do you see that?

A Yes.

Q Has NIH taken any action to implement that sentence of Section 3(e)?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion.

BY MR. McGINTY:

Q You can answer.

A Discussions are -- have been had, about identifying agency priorities.

Q Okay. What is the relationship between agency priorities and that last sentence of Section 3(e)?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A To be honest, I do feel like I'm now using my own thoughts to tell you that, and I don't know that that is the correct way to answer that question.

Q Well, you told me that discussions had been had about identifying agency priorities. Was that your testimony?

A That is my testimony.

Q Okay. Where do those agency priorities come from?

A The director of the agency.

Q Okay. And what has the director of the agency told you about those agency priorities?

A The director hasn't told me anything. The director is developing a memo to communicate agency priorities, but there's nothing final, so we don't have agency priorities final yet.

Q Well, grants have been terminated on the

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?

A Provided my supervisor with the instruction.

Q And you don't know if that came from Rachel Riley or not?

A I don't.

Q This letter that's been marked as Exhibit 4 has similar language as the Executive Order that's in Exhibit 3. Do you agree with that?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A Are you asking me if I -- I haven't compared.

Q Okay. Let's take a look at Executive Order 14168. Do you see in Section 2 where it says:

"These sexes are not changeable and are grounded in fundamental and uncontrovertible reality"?

A Yes.

Q And do you see in the letter of February 28th where it says:

"Many such studies ignore rather than seriously examine biological realities"?

A Yes.

Q That seems pretty similar, doesn't it?

MS. ANDRAPALLIYAL: Objection, calls for speculation, calls for a legal conclusion.

BY MR. McGINTY:

Q You can answer.

A Looking at it today, it looks the same.

Q Going back to the language in the Order, you write: It's true -- or, rather, you write that "Research programs based on gender identity" -- or in this letter it says -- "are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans."

Has NIH done any study whatsoever to see if that's true?

A I don't know.

Q Would you know if they had done?

A I'm not sure.

Q Okay. When did it become the policy of NIH not to prioritize research programs based on gender identity?

A I don't know.

Q So earlier I thought you testified that one of your jobs at NIH was supervising the Division of, I think you said, Grants Policy. Is that correct?

A Correct.

Q So would you know what the grant policies are at NIH?

A I would.

Q And you don't know when it became the policy of NIH to deprioritize the funding of transgender issues?

A I do not.

Q Why not?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Final priorities have not been provided. I don't know.

MR. McGINTY: Okay. Happy coincidence, mark this as Exhibit 5, please.

(Bulls Deposition Exhibit 5 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 5. And I'll represent to you that this is an article from the journal Nature that I've printed out. And I want to direct your attention to pages 4 and 5.

There are some cutouts here, or maybe callout boxes, but seems to be a portion of the

Staff Guidance - Award Assessments for Alignment with Agency Priorities.

Do you see that?

A Yes.

Q Is this the document that we were talking about before when we were talking about Exhibit 1?

A Yes.

Q And you have -- this is a real document, it exists in NIH, right?

A It's a real document.

Q Okay. And how have you used it?

A To provide guidance to the ICs.

Q Okay. Where did it come from?

A What do you --

Q Who wrote it?

A I wrote it, along with my deputy, yes.

Q Okay. You wrote this document?

A Yes.

Q Okay.

A I developed it.

Q Along with your deputy. Who is that?

A Kristen Ta.

Q Can you spell that for me.

A T-A.

Q Great. So this includes, on page 5, that

transgender issues language. Do you see that?

A Yes.

Q Did you write this?

A Yes.

Q Okay. I'm trying to understand, because earlier on Exhibit 4 you said you didn't write any word on that letter, and that included this transgender issues language, didn't it?

A I didn't write any word on that letter.

Q Okay. So where did this "transgender issues" language come from?

A The categories from that letter.

Q I see. I think I see. Let me confirm.

You were given template letters, you cut and past from those template letters into this Staff Guidance document?

A Correct.

Q What's the purpose of this Staff Guidance?

A To help ICs to figure out how to fund or, you know, yes, provide funds and how to protect the categories. If the DEI was the sole purpose, then, you know, they don't make awards categories to us, where we were trying to make sure that they worked with the recipient to come to a mutual negotiation.

Q Okay. So this --

A This is guidance.

Q Guidance to?

A The ICs.

Q To the ICs for the purposes of making decisions about future awards?

A Making decisions on their portfolio, including current awards, just their entire portfolio.

Q Including current awards and future awards?

A Correct.

Q Okay. And so would this guidance instruct ICs to terminate some awards?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion and calls for speculation.

BY MR. McGINTY:

Q You can answer.

A This is, again, draft guidance. And the guidance is to provide the ICs with an opportunity to know the various categories and how to address those.

Q Okay. Let's go through those categories. What is Category 1?

A Category 1 just requires for them to -- the sole purpose of the award is DEI, like we just

were talking about. The sole purpose of the award is DEI, just a diversity supplement.

Q Okay. And, first of all, what does DEI mean?

A Diversity, equity, and inclusion.

Q Okay. Yeah, but what makes an award DEI or not?

A Oh.

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't have the programmatic expertise to make that determination in terms of the research and how it's reviewed. This is for ICs to use and make those determinations.

BY MR. McGINTY:

Q Okay. Is there any NIH policy for ICs to make a determination as to whether an award is a DEI award or not?

A There are some awards that are specifically, the sole purpose of the award is DEI. So there has to be a programmatic rationale which is outlined in either the Notice of Funding Opportunity.

Q And are those the only awards that would fit into Category 1?

A DEI awards?

Q Well, I'm trying to figure out -- yeah, yes.

A Yes, those would be the -- the award cannot stand without -- the sole purpose of making the award was to support DEI activities.

Q Okay. And you're not sure whether or not an award is DEI or not?

A The guidance is for them to take a look, to use it to make determinations within their portfolio as to whether or not it's a DEI award.

Q Okay. So this talks about diversity supplements or conference grants where the purpose of the meeting is diversity. That's what you are talking about here?

A That's what I'm talking about.

Q And is that the only kind of award that would fit into Category 1?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: It's the example given.

BY MR. McGINTY:

Q Okay. Are there other kinds of awards that would fit into Category 1?

MS. ANDRAPALLIYAL: Objection, calls

speculation.

THE WITNESS: That's for the IC to determine.

BY MR. McGINTY:

Q Okay. How is the IC supposed to determine that?

A Looking at their portfolio and looking at why the grant was made.

Q Is there a definition of DEI anywhere?

A I don't know.

Q Would you know?

A I would know.

Q Okay. Okay. So in Category 1 they're supposed to terminate the award, right --

A Yes.

Q -- and not fund it?

A Category 1 is that they cannot fund the award.

Q Okay. And then, so what's Category 2?

A Where the DEI activity is ancillary to the entire purpose of the award, so it just has pieces that can be excised, but the award can still -- it's still, you know, viable without the DEI activities.

Q Okay. And what are they supposed to do with a Category 2?

A The assessments that we talked about earlier, take those and determine whether or not and assess their portfolio to see how they can save the award.

Q Okay. And, again, there's no definition of DEI that you're aware of that they would use to do that?

A I'm sure there's a definition of DEI within the various, what do you call it, activities -- no, grant activities. I don't know if there's a DEI standard definition across the -- a policy definition, but definitely a programmatic definition.

Q What's the difference between those two things?

A Well, a policy definition would be from the central and, you know, it would be more administrative, so I don't have administrative DEI. But for the purposes of the research, there might be programs where there is either, you know, statutory language that defines DEI or that the program defines it, DEI, which is more on the scientific, programmatic side.

Q Okay. So if I'm understanding you correctly, there might be a definition within each

one of the ICs that defines DEI?

A It might be a scientific definition that is used by all ICs.

Q And you wouldn't be aware of it?

A Not in the sense of issuing the Staff Guidance. In other words, I needed them to take that -- the guidance is for them to use and to make those assessments, not for me to tell them.

Q Did anyone tell you to write this guidance?

A Yes.

Q Who told you to write the guidance?

A The guidance was -- well, nobody told me to write it. The guidance was requested.

Q Okay. By whom?

A By the Grants Management officials and -- yeah, by the Grants Management officials.

Q Grants Management, are these the same as the --

A The Chief Grants Management Officers within the funding, IC.

Q Okay. And why did they ask for the guidance?

A So they could begin making, you know, begin looking at how they can issue awards.

Q Did something happen to make them think that they needed guidance?

A I think people were --

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Yeah, I'm thinking, you know. I don't -- yeah, that's really an assumption.

BY MR. McGINTY:

Q Well, I'm just trying to figure this out, right, because people don't ask for guidance for no reason.

Did anyone tell you why they wanted the guidance?

A Yes, so that they could know, to make sure that they were able to know what awards to fund and how to make determinations on how funding would be made under the DEI activities.

Q Was there any communication prior to this guidance indicating that DEI activities would not be funded?

A There was a funding pause that was placed on the agency, so they wanted to understand what could be funded.

Q So this is in response to the funding pause?

A Yes.

Q Did you talk with any of your supervisors about this guidance?

A Yes.

Q And who did you talk to?

A Liza Bundesen.

Q Did you talk with Dr. Memoli?

A No.

Q Okay. All right. How about any future version of this guidance?

A Liza briefed Dr. Memoli.

Q Okay. And how many conversations have you had with Dr. Bundesen about it?

A I don't recall how many. It was frequent.

Q Okay. And what did you talk about?

MS. ANDRAPALLIYAL: Objection. To the extent that the question is calling for the provision of deliberative information, I would instruct the witness not to answer.

BY MR. McGINTY:

Q Did Dr. Bundesen draft any part of this?

A No.

Q Did she review a draft?

A Yes.

Q And did she approve it?

A It wasn't final, it was still ongoing, so the portions that she reviewed, she -- we just discussed.

Q Okay. How did you go about writing this guidance?

MS. ANDRAPALLIYAL: Objection. To the extent the question is calling for deliberative information, I instruct the witness not to answer.

BY MR. McGINTY:

Q Did you examine any existing NIH policies?

A I'm sure I did. I'm sure I looked at the policy statement and -- the Grants Policy Statement, just to see if there was anything in there that we could use.

Q And there's no citation to the Grants Policy Statement in here, is there?

A No.

Q Okay. Did you look at anything else?

MS. ANDRAPALLIYAL: Objection. To the extent the question is calling for specific and deliberative information, I instruct the witness not to answer.

BY MR. McGINTY:

Q Did you examine any Executive Orders prior to writing this guidance?

A Of course I read the Executive Orders.

Q And you said, "of course." Why did you say of course?

A Because I needed to be aware.

Q Why did you need to be aware?

A Because that's information that I needed to know, or at least review, as the discussions were taking place.

Q Because it's obvious, isn't it, that the Executive Orders are causing this to happen?

MS. ANDRAPALLIYAL: Objection, legal conclusion, calls for facts not in evidence, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A I don't know that it's obvious, but I definitely read the Order, all of the Orders.

Q So going back to page 5 of this Nature article and the guidance that you wrote, looking at Appendix 3, and it says:

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

Do you see that?

A Yes.

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.

Do you recognize this document?

A Yes.

Q And what is it?

A The draft Staff Guidance.

Q And this is a little bit later than the Exhibit 5 we were just looking at, right?

A Correct.

Q This one is dated March 25, 2025. Is that right?

A Yes, yes.

Q Did you write this one, too?

A Yes.

Q And when did you write this one?

MS. ANDRAPALLIYAL: Can we go off the record, please.

(Discussion off record)

(Recess taken - 11:06 to 11:31 a.m.)

BY MR. McGINTY:

Q You understand you're still under oath?

A Yes.

Q Okay. So continuing to look at what we marked as Exhibit 6, I think earlier you testified that you wrote this document.

A Yes.

Q And why did you write this document?

A To help the Institutes and Centers with trying to figure out how to make awards, give them guidance.

Q Okay. Give them guidance on making awards and also terminating awards, right?

A Making awards and making assessments on which categories they need to use to make those assessments.

Q Okay. So this says, under Category 1, "Add the action to the master spreadsheet"?

A Yes.

Q What's the master spreadsheet?

MS. ANDRAPALLIYAL: Objection. To the extent the question calls for information that's deliberative, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q How does NIH keep track of the grants it has terminated?

A We do track it in a spreadsheet.

Q Okay. And what's on that spreadsheet?

MS. ANDRAPALLIYAL: Objection. To the extent that the question is calling for information that's deliberative and not final, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q Okay. Does the spreadsheet contain information about grants that have been terminated?

A Yes.

Q Okay. And do you use a spreadsheet to keep track of that?

A Yes.

Q Okay. Does the spreadsheet indicate the reason that the grants were terminated?

A Based on the categories, yes.

Q Okay. And that's the Category 1, 2, 3, 4 you have here?

A No. The categories that were provided in the termination letters.

Q Okay. And which categories are those?

A The categories of the DEI --

Q Okay. So going --

A -- China.

Q -- back to --

A Yeah.

Q -- what I think had been marked Exhibit 5, page 5 of Exhibit 5?

A Yes.

Q So you're looking at China, DEI, and transgender issues?

A Yes.

Q Are there any other categories that designate the reason that a grant was terminated?

A Vaccine hesitancy is the one additional one.

Q Any others?

A No.

Q Okay. And how do you know which of those categories to terminate a grant under?

A Based on the letters that are provided to -- you know, the list. We receive a list.

Q That's the list you get from Rachel Riley?

A That's the list that I get from my supervisor or, yeah, it's forwarded.

Q Okay. And does that list show which category reason to terminate the grant for?

A Yes.

Q Okay. How does it do that?

A It has a category section.

Q What's the form of this list?

A It's a spreadsheet.

Q It's a spreadsheet. Okay.

A So our spreadsheet matches that spreadsheet.

Q Did you, like, copy and paste into it?

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

BY MR. McGINTY:

Q Okay. So you get a spreadsheet that tells you which grants to terminate and the reasons why?

A Yes.

Q And what are those reasons?

A Based on the categories.

Q Is it verbatim what I'm seeing her, China, DEI --

MS. ANDRAPALLIYAL: Objection. To the extent that this is calling for deliberative information that has not been finalized, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q Speaking only about grants that have actually been terminated, the spreadsheet that you get, what does it say for the reason that the grants have been terminated?

A The categories, you know, DEI, transgender, you know.

Q Is that verbatim?

A I don't -- I can't tell you verbatim, but

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

Disparity Institute?

A I don't know.

Q Okay. So this March 25 Guidance says it is rescinding the March 13 Guidance. Is that right?

A Yes.

Q So the March 25 Guidance kind of takes the place of this March 13?

MS. ANDRAPALLIYAL: Objection. This is a draft so I'm instructing the witness not to answer as to deliberative information that has not been finalized.

BY MR. McGINTY:

Q The March 25 Guidance has an issue date of March 25, right?

A It does say that, but it is not final.

Q Has this been given to ICs?

A It was shared for feedback.

Q Oh, with whom?

A The ICs.

Q Okay.

A Yeah.

Q And the ICs have not implemented it yet?

A I cannot say that they have implemented the guidance. What they've been told is that we cannot give them final guidance until we receive the

final details from the director.

Q So earlier you talked about, I think, three versions of this document. This March 25 one, which version is this?

A The latest.

Q This is the latest?

A Mm-hmm, yes.

Q And the one that's in the Nature article, which one is that?

A It looks like it might be --

MS. ANDRAPALLIYAL: Objection. To the extent that the question is seeking deliberative information that has not been finalized yet, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q You said the first one was used by ICs to implement policy, right?

A To implement guidance on how to unpause funding.

Q Was the one in the Nature article used by ICs to implement guidance on how to unpause funding?

A The -- it expanded on the original guidance as we received the draft memo on the priorities. We wanted to make sure that when the -- as the memo came out, that they had an understanding

of the next steps in the guidance. So the guidance just expanded based on the anticipation of receiving the memo.

Q Okay. So this February 13th one is the first. Is that right?

A Yes.

Q And then the one in the Nature article is the second. Is that right?

A Yes.

Q Okay. And the March 25 one is the last one?

A I believe so, yes.

Q Okay.

MS. ANDRAPALLIYAL: Objection to the draft. So I object to the extent that the information sought is seeking final information that has not been finalized yet.

MR. McGINTY: I think privilege has been waived, Counsel.

MS. ANDRAPALLIYAL: The deliberative process privilege does not have a subject matter waiver component to it.

(Reporter requests clarification)

MS. ANDRAPALLIYAL: The deliberative process privilege does not have a subject matter

waiver component to it.

MR. McGINTY: Would you mark this. I think we're on 8.

(Bulls Deposition Exhibit 8 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 8. Do you recognize this document?

A Yes.

Q And what is this?

A A memo that Dr. Lauer and I sent asking, alerting folks that we were evaluating our agency priorities for the new administration.

Q And this one says, "We recognize that NIH programs fall under recently issued temporary restraining orders," and there's a list of some cases, right?

A Mm-hmm.

Q Why was that included in here?

MS. ANDRAPALLIYAL: Objection. The question calls for attorney-client communications, it's privileged. I'd instruct the witness not to answer.

BY MR. McGINTY:

Q By issuing this guidance you were alerting

the programs that there were temporary restraining rules that apply, right?

A Yes.

Q Okay. In any of the subsequent guidance did you alert the programs that there were temporary restraining orders that applied?

MS. ANDRAPALLIYAL: Objection. The question seeks deliberative information. I instruct the witness not to answer.

BY MR. McGINTY:

Q Let's see. Going back to what I think is Exhibit 6, March 25 Guidance, were ICs given any guidance to avoid the termination of grants to institutions providing gender affirming care in plaintiff states in this case?

MS. ANDRAPALLIYAL: Objection, information seeks -- the question seeks information that's deliberative, not final, and potentially attorney-client privileged, so I'm instructing the witness not to answer.

BY MR. McGINTY:

Q Has NIH terminated grants to institutions that provide gender affirming care in the plaintiff states in this case?

MS. ANDRAPALLIYAL: Objection, calls for a

legal conclusion.
BY MR. McGINTY:
Q You can answer.
A I don't -- I don't know of an institute or center that has terminated a grant based on this information in this guidance.
Q Okay. That's because you get the lists of grants to terminate from outside of NIH, right?
A Yes, it -- yes, the list comes from outside of NIH.
Q So what has this guidance been used to do, if anything?
A To anticipate the memo of the priorities. ICs have not been instructed to terminate grants.
Q So grant terminations are coming exclusively from outside of NIH?
A Yes.
Q Okay. Let's see.
(Bulls Deposition Exhibit 9 was marked for identification.)
BY MR. McGINTY:
Q Exhibit 9, do you recognize this document?
A Yes.
Q And just for the record, we're on Exhibit 9. And what is it?

A It's a Notice of Award.

Q And who is it a Notice of Award to?

A Seattle Children's Hospital.

Q And this is the same grant that we were talking about, I think, on Exhibit 2, maybe Exhibit 3?

A Yes.

Q Now, could you just run through the table that appears on page 1 of this exhibit.

A The table?

Q Yeah, there's some numbers there. I'm not entirely sure how to follow it.

What does this table indicator mean?

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

BY MR. McGINTY:

Q Do you know how to interpret this table?

A What? There -- it looks like tables. Are you talking about this table?

Q Sorry. I mean the table entitled, "Summary Federal Award Financial Information."

A Okay.

Q Sorry. Sorry for my confusion.

A Okay. Yes, I can tell you that the -- it's the budget start date -- you know, the budget

period start date from when the grant started and the end date for when the grant ended. Then, you know, it has the obligation of funds and it's the deobligation.

Q And what is that, deobligation?

A Removing funding, the existing funding, from the grant.

Q Okay.

A And then the total amount that's obligated is the amount that was left on the award, it looks like. So it looks like they didn't deobligate the entire. There was money left for the recipient. And the project period end date which is, at the time, the entire life cycle of the grant project.

Q And so how much was deobligated?

A I -- I can only assume the amounts here. I didn't deobligate it, but I'm looking at the table.

Q According to this table, how much was deobligated?

A Yeah, well my math is bad so.

It's the 200 -- 200,453, 162,636, and the 37,000 it looks like it was -- those all have minus signs, so that tells me that they deobligated that amount, and the remaining left is the 40,000.

(Reporter requests clarification)

THE WITNESS: 40,091.

BY MR. McGINTY:

Q Okay. Thank you.

So who issued this letter?

A Margaret Young. It's not a letter. It's a Notice of Award.

Q Okay.

A Yeah. I just wanted to make that distinction.

Q No, I appreciate it.

So Margaret Young issued this Notice of Award?

A Yes.

Q Who is Margaret Young?

A She is the Chief Grants Management Officer of Child Development, NICHD.

Q Okay. If you would turn to page 5.

A Yes.

Q There's some language here under "Termination" and "Transgender Issues."

Could you read the language under Termination?

A "This award related to 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."

Q Who wrote that language?

A That language was taken from the termination letter that I sent on the 28th. The termination letter went out, had that language, and then I instructed her to issue the Notice of Award using the same language.

Q Okay. Why did you instruct her to do that?

A That's the process for terminating awards, is issuing the letter and then the institute will -- well, this process is the issuing of the termination letter, but the award is the official document.

Q So why did you instruct Margaret Young to take the language from the termination letter?

A Because we were asked to terminate the awards, of the award, other awards.

Q Could you have used different language?

MS. ANDRAPALLIYAL: Objection. To the extent the question is calling for the provision of deliberative information that wasn't actually finalized into this letter, I'm instructing the

witness not to answer.

BY MR. McGINTY:

Q Did anyone tell you to use this language exactly?

A I consulted with OGC.

Q Office of General Counsel?

A Correct.

Q And under "Transgender Issues," this language is also identical to the language from the termination letter?

A Yes.

Q And did anyone tell you to use this language exactly?

A No. The language matched the language in the letter, so I just followed the guidance from the letter and advised that the award matched the letter.

Q It's kind of --

A I didn't have any other language to give.

Q It's kind of a funny typo under "Termination." "Transgender issues" is capitalized on the "T." Do you know why that is? Under "Termination," sorry.

A Oh.

(Witness reviews document)

THE WITNESS: No, I don't know.

BY MR. McGINTY:

Q Could it have been copied and pasted from something?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know.

BY MR. McGINTY:

Q Is it standard practice to capitalize the "T" on these Notice Awards?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: The "T"?

BY MR. McGINTY:

Q On "Transgender issues."

A I've not issued an award for a letter that -- before.

Q Have you told anyone to capitalize that "T"?

A The language was taken from the letter.

(Bulls Deposition Exhibit 10 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 10. Do you recognize this document?

A A Notice of Award.

Q And it's the same grant as we were talking about in Exhibit 9, isn't it?

A Yes.

Q And taking a look at that, "Summary Federal Award Financial Information," could you tell me what that summary means?

A It looks like the deobligations were reversed.

Q Do you know why the deobligations were reversed?

MS. ANDRAPALLIYAL: Objection, asks for speculation.

MR. McGINTY: I asked if she knew.

THE WITNESS: If I knew why?

BY MR. McGINTY:

Q Why the deobligations were reversed.

A To reinstate the grant.

Q Do you know why this grant was reinstated?

A No, but I was asked to reinstate the grant.

Q Who asked you to reinstate it?

A I want to say my supervisor. This is the acting supervisor.

Q And who is that?

A Dr. Lorsch.
Q Dr. Lorsch?
A Yeah.
Q Do you know when that happened?
A Probably around the same day or the day before of the issue date of the letter.
Q And this grant was originally terminated in response to one of those lists you got, right?
A Yes.
Q Has any other grant been reinstated since you got a Notice to Terminate on one of those lists?
A Yes.
Q Which ones are those?
A I think it's a COVID grant, the COVID OT of the transaction.
Q COVID OT. Do you know what grantee?
A I don't know.
Q Go to page 5 in Exhibit 10.
MS. ANDRAPALLIYAL: Can we go off the record, please.
(Discussion off record)
MR. McGINTY: Back on the record.
BY MR. McGINTY:
Q So we're on page 5, and it says:
"Revised Award: This grant has been

restored and the termination clause rescinded effective immediately. This grant will continue under the original no cost extension."

What does that mean?

A It means that the grant was restored, you know, and that the termination was rescinded, and when the grant was terminated, it was in a no cost extension. And we were just saying that we wanted the recipient to know that they can continue in their extension.

Q Okay. It does say:

"The previous terms and conditions of award remain in effect as stated below."

What does that mean?

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

BY MR. McGINTY:

Q You can answer.

A I don't know what that means. It just -- I don't know.

Q Okay. Because it says "Termination," and it has the same language related to transgender issues. It says:

"Transgender issues: Research programs

based on gender identity are often..."
(Reporter requests Mr. McGinty to read slower)
MR. McGINTY: Sorry, of course.
BY MR. McGINTY:
Q It has the same language from the letter we were talking about earlier.
A Yes.
Q Do you know why that language is still there?
A I don't.
Q Is this grant subject to being defunded again because of what it researches?
MS. ANDRAPALLIYAL: Objection, calls for speculation.
THE WITNESS: No.
BY MR. McGINTY:
Q It's not?
A Not that I am -- not that I would say, no.
Q Is it part of your duties as the Director of OPERA to interpret Notice of Awards like this?
A Yes.
Q So how would you interpret this Notice of Award when it says, "The previous terms and conditions will remain in effect as state below,"

and it still has the "Termination" and "Transgender issues" language?

A I would interpret it that someone didn't delete the language, because when we typically revise awards, the previous terms and conditions still apply. So I believe that it was in error.

Q And going back to page 1, was that also issued by Margaret Young?

A Yes.

Q Did you ask Margaret Young to issue this NOA?

A The recension of the termination, yes.

Q And did you give her any particular instructions with respect to the "Termination" and "Transgender issues" language?

A I told her to revise the award and restore the grant and sent her the language to restore the grant.

Q And that's the language -- which language is that?

A "This grant has been restored and the termination clause rescinded effective immediately. The grant will continue under the original no cost extension."

Q Did you get that language from anywhere?

A No.

Q You wrote that?

A I wrote it.

MR. McGINTY: We can go off the record.

(Luncheon recess taken -- 12:03 to 1:08 p.m.)

MR. McGINTY: Back on the record. Go ahead and mark this, please.

(Bulls Deposition Exhibit 11 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 11. Do you recognize this document?

A Yes.

Q And what is it?

A A termination letter.

Q And this is another one that you wrote, right?

A This is another one that I issued that was written.

Q I'll clarify. You signed this, right?

A Correct.

Q Okay. And you signed this on behalf of Margaret Young?

A Yes.

Q And that's the same Margaret Young that we

were talking about earlier, the Chief Grants Management Officer at NICHD?

A Yes.

Q Why did you issue this on behalf of Margaret Young?

A I believe at that time because the letters were coming out quickly that I just issued them on behalf of the IC Chief GMO, and then they would handle the Notice of Reward.

Q Did you talk to Margaret Young, before you issued it, about issuing this letter?

A No.

Q Is this another one of the letters that you got in a list?

A Yes.

Q And that list was sent to you by your supervisor?

A Yes.

Q Who at the time was?

A March 12th? I can't recall.

Q Okay. And do you recall whether or not Rachel Riley was cc'd on the e-mail you got that terminated this grant as well?

A I don't recall --

Q Okay.

A -- Rachel being on there.

Q You'd have to look at the e-mail to know?

A Yes.

Q And you did get this in an e-mail from your supervisor?

A An e-mail from my supervisor, a forwarded, probably.

Q A forwarded e-mail from your supervisor that had the spreadsheet that you were talking about earlier?

A All of them have spreadsheets.

Q And that spreadsheet has the list of grants to terminate?

A Yes. And a point of clarification, if I may?

MS. ANDRAPALLIYAL: Sure.

THE WITNESS: Because the process was just continuing to be a lot, we actually -- I did say to the -- I asked the Chief Grants Management Officers if they were okay with me just issuing the letter and them issuing the Notice of Awards. And they did say that they were okay with that. And I do have some of that in writing.

BY MR. McGINTY:

Q Great. Thank you for that clarification.

A Yeah.

Q By way of further clarification, did you have any input in saying whether or not this particular grant was going to be terminated?

A No.

Q And did you have any input in the language on this letter?

A No.

Q To your knowledge, did anyone at NIH have input?

MS. ANDRAPALLIYAL: Objection. It calls for the provision of deliberative information. I'm instructing the witness not to answer.

MR. McGINTY: Counsel, deliberative process exemption only applies where an action has not been taken. I'm talking about terminating a grant.

MS. ANDRAPALLIYAL: No, that's not true. The deliberative process privilege applies to pre-decisional communications that precede a final action, so it does apply to actions that have already been taken.

BY MR. McGINTY:

Q Is there anything other than this letter that explains why the grant was being terminated?

A The spreadsheet.

Q The spreadsheet explains why?

A It doesn't explain, it just lists the category.

Q Okay. Is there anything other than this letter and the spreadsheet?

A An e-mail.

Q An e-mail?

A Yes.

Q An e-mail you got from your supervisor?

A Yes.

Q Anything other than this letter, that spreadsheet, and the e-mail?

A No.

Q Okay. Were either the spreadsheet or the e-mail shared with the grant recipient?

A No, not that I'm aware of.

MR. McGINTY: Mark this, please.

(Bulls Deposition Exhibit 12 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 12. And do you recognize this document?

A Yes.

Q And what is it?

A Termination letter.

Q And this is another termination letter that you signed?

A Yes.

Q And this one is to the Regents of the University of California, San Francisco. And it's Project No. 1R01 AI186641-01 --

(Reporter requests clarification)

MR. McGINTY: I'm sorry. 1R01 AI186641-0.

BY MR. McGINTY:

Q Is that correct?

A Dash 01.

Q And is this another one of the terminations that you got in a list?

A Yes.

Q From your supervisor?

A Yes.

Q And this letter is dated March 18?

A Yes.

Q And who was your supervisor at that time?

A I believe it was Jon Lorsch at that time, for sure.

Q Jon Lorsch?

A Dr. Lorsch.

Q Dr. Lorsch?

A Yeah.

Q And, to your knowledge, did anyone at NIH have any input in whether or not this grant was going to be terminated?

A I don't know.

Q Would you know?

A I don't know.

MS. ANDRAPALLIYAL: Objection, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A I wouldn't know.

Q And is there anything, other than this letter, that explains why this grant was terminated?

A The spreadsheet, the e-mail.

Q Anything else?

A No.

Q Okay. Did you ever talk to Dr. Lorsch about this termination?

MS. ANDRAPALLIYAL: Go ahead.

THE WITNESS: No.

BY MR. McGINTY:

Q Did he tell you why this grant was being terminated?

MS. ANDRAPALLIYAL: Objection. Because

the question is seeking deliberative information, I instruct the witness not to answer.

BY MR. McGINTY:

Q Let's go back very quickly to Exhibit 11. I just want to make sure that the grant project number is on the record.

Could you read that for me.

A Can I read -- I'm sorry?

Q The project number that was being terminated.

A Oh. 5 U01 HD108779-04.

Q Great. And to whom -- what was the institution this was issued to?

A Regents of the University of Minnesota.

Q Thank you.

MR. McGINTY: Mark that one, please.

(Bulls Deposition Exhibit 13 was marked for identification.)

BY MR. McGINTY:

Q I hand you what's been marked Exhibit 13. Do you recognize this document?

A Yes.

Q And what is it?

A A termination letter.

Q Okay. And this one is a grant to the

Regents of the University of Colorado. Is that right?

A That is correct.

Q And could you read the project number for me, please.

A Sure. 1R21 HD115838-01.

Q And this is another one that was provided to you in a list from your supervisor?

A Yes.

Q And the only thing to explain why that grant was terminated is this letter, the spreadsheet that was attached to that e-mail, and the e-mail itself?

A The e-mail itself doesn't explain it, it just asks me to terminate it. The spreadsheet attached gives the category and the grant number.

Q Okay. And, to your knowledge, NIH didn't do any assessment of this particular grant before it was terminated?

A I don't know.

MR. McGINTY: Mark that, please.

(Bulls Deposition Exhibit 14 was marked for identification.)

BY MR. McGINTY:

Q I hand you what's been marked Exhibit 14.

Now, starting about halfway down the page, this appears to be an e-mail from you. Is that right?

A Yes.

Q And what is this e-mail from you?

A A termination letter.

Q And did you start sending these in the form of an e-mail at some point?

A Yes.

Q When was that?

A Likely around the same date of this letter.

Q Which is March 21, 2025?

A Yeah, around that time.

Q And why did you do that?

A To be efficient.

Q Why did you need to be efficient?

A The letters were -- the spreadsheet had many terminations on the list, so I did it to be efficient.

Q It was easier to send it in e-mail form because there were so many to do?

A Yeah.

Q And who is the institution that this grant was issued to?

A University of Washington.

Q And what's the project number?
A 5R01MD017573-03.
Q Okay. And this one, I think you alluded to it already, but this one is also on the basis of the spreadsheet that you got?
A Yes.
Q And who sent you that spreadsheet?
A Probably it was forwarded to me by my supervisor.
Q Forwarded from whom?
A From Dr. Memoli.
Q Dr. Memoli?
A Yeah, at this point. That's correct.
Q And do you know if it was forwarded to Dr. Memoli from anybody?
MS. ANDRAPALLIYAL: Objection, calls for speculation, calls for a provision of deliberative information.
BY MR. McGINTY:
Q You can answer.
MS. ANDRAPALLIYAL: Objection. To the extent that it calls for the provision of deliberative information, I would instruct the witness not to answer.
MR. McGINTY: Can you explain the

privilege attaching to an e-mail that the person forwarded an e-mail.

MS. ANDRAPALLIYAL: To the extent that the answer is -- that the answer would provide information that is deliberative, I would instruct the witness not to answer.

BY MR. McGINTY:

Q Did any of the to or from or cc fields on that e-mail, or on the e-mails that were attached to it, contain back-and-forth deliberative discussions?

A Not that I'm aware of.

Q Okay. Do you recall if the e-mail that Dr. Memoli -- was forwarded from Dr. Memoli, was forwarded from anybody else?

A I don't recall.

Q Okay. The only way to know that would be from the e-mail?

A Yes.

Q Okay.

MR. McGINTY: Mark that.

(Bulls Deposition Exhibit 15 was marked for identification.)

BY MR. McGINTY:

Q I pass you what has been marked Exhibit 15. Do you recognize this document?

A Yes.

Q What is it?

A It is a termination letter.

Q And this is two-sided. I'm sorry, I printed this double sided.

A That's okay.

Q And that's your signature at the end, right?

A Yes.

Q Okay. And this is another one of the terminations on the basis -- that was sent to you on a spreadsheet?

A Yes.

Q And what's the institution that received this grant?

A University of Washington.

Q And what's the project number?

A 1F31 AI181431-01A1.

Q Okay. And the only thing that would explain why this grant was terminated is this letter and the spreadsheet?

A Yes.

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

BY MR. McGINTY:

Q What are the documents that would explain why this grant was terminated?

A The letter, the e-mail that was forwarded with the spreadsheet.

Q And that spreadsheet was forwarded to you from your supervisor?

A Yes.

Q And who is your supervisor at the time?

A I believe it was Dr. Lorsch. There was a transition period so.

Q So either Dr. Lorsch or?

A Dr. Bundesen.

Q Okay. Either Dr. Lorsch or Dr. Bundesen.

And would Rachel Riley have been on any of the to or from fields of that e-mail?

A Not at that time, not during this time period.

Q Anyone else from HHS?

A No.

Q So did -- so that stopped at some point?

A Yes. I didn't see the to, where it originated. It was just coming from Dr. Memoli to either Liza or Dr. Lorsch.

Q And when did you stop being able to see where it originated?

A I don't even recall because I stopped looking down on the e-mails at that point. It was -- yeah.

Q Before or after March 10?

A Probably after.

Q Sometime after March 10?

A Yes.

(Bulls Deposition Exhibit 16 was marked for identification.)

BY MR. McGINTY:

Q I'm showing you what's been marked Exhibit 16. Do you recognize this?

A Yes.

Q And what is it?

A A termination letter.

Q And this is another one that you signed?

A Yes.

Q And who is the recipient of this grant?

A University of Washington.

Q And what's that project number?

A 5R01LM013301-05.

Q And this is another one that came to you in the form of a spreadsheet listing the grants to terminate?

A Yes.

Q And that was sent to you by your supervisor?

A Yes.

Q Which was who at this point?

A Dr. Lorsch.

Q That was Dr. Lorsch.

And you wouldn't have known who sent Dr. Lorsch this spreadsheet?

A Typically, like I said, I started seeing just the e-mail forwarded from -- sent to Dr. Lorsch from Dr. Memoli.

Q Got it.

A Yeah.

Q So Dr. Memoli sent it to Dr. Lorsch. Is that right?

A That is correct.

Q Okay. And do you know who sent it to Dr. Memoli?

A No.

Q Okay. Because that information was cut off of the e-mail?

A I don't know if it was cut off, it just wasn't there.

Q It wasn't on the e-mail?

A No, it wasn't on the e-mail.

Q Okay.

(Bulls Deposition Exhibit 17 was marked for identification.)

BY MR. McGINTY:

Q I'm handing what's been marked Exhibit 17. Do you recognize this?

A Yes.

Q And what is this?

A A termination letter.

Q And who is the institution it was issued to?

A University of Washington.

Q And what's the project number?

A 1G13LM014426-01.

Q And this is another one that you got in a spreadsheet?

A Yes.

Q And it was sent to you by your supervisor?

A Yes.

Q And do you know who sent the spreadsheet to your supervisor?

A During this period it was from Dr. Memoli to -- I -- this is the foggy period, sorry.

Q Okay. You're not sure who your supervisor was?

A I'm sure who my supervisor was. I'm just not sure of the period when it was, the different time frames.

Q That's fine. It was either Bundesen or Lorsch?

A Right.

Q And do you know who sent it to Dr. Memoli?

A I don't recall during this time. Yeah, I'm not sure if it was just forwarded from Dr. Memoli to Liza or Jon to me. Because, remember, during a period of time, it was on the from with -- how do I say? The person that it was sent from at the department was on there, and at a point that stopped.

Q But when it was from someone from the department, that was Rachel Riley?

A The two times, yes.

Q Okay. Was there anyone else from HHS it was sent from?

A Not that I'm aware of.

Q Okay. So either it was Rachel Riley or you didn't have the information?

A Correct.

Q Okay. And this letter and the other letters we've been looking at, this is still the

same template letter that was provided to you?

A Yes.

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

A No, just signed it.

Q Okay. And the only thing that would explain why this grant was terminated is this letter and the spreadsheet and the e-mail?

A Yeah, the spreadsheet that was attached to the e-mail.

(Bulls Deposition Exhibit 18 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 18. Do you recognize this?

A Yes.

Q And what is it?

A A termination letter.

Q And this is another one that looks like it was in e-mail form. Is that right?

A Yes, that's correct.

Q And who is the institution it was issued to?

A University of Washington.

Q And what's the project number?

A 1R21AI183907-01A1.

(Reporter requests clarification)

THE WITNESS: "A" as in apple.

BY MR. McGINTY:

Q And this is another termination that you issued on the basis of a spreadsheet that was sent to you?

A Yes.

Q And that was sent to you -- who sent you that spreadsheet?

A Dr. Lorsch.

Q Dr. Lorsch sent it to you. And Dr. Memoli sent it to Dr. Lorsch?

A Correct.

Q And the only thing that would explain why this grant was terminated is this letter and the e-mail and the spreadsheet?

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

BY MR. McGINTY:

Q What are the documents that would explain why this grant was terminated?

A The letter, the forwarded spreadsheet that had the categories in there.

Q Okay. Anything else?

A No.

MS. ANDRAPALLIYAL: Can we go off the record for a minute.

MR. McGINTY: Why?

MS. ANDRAPALLIYAL: I would like to confer with my co-counsel.

MR. McGINTY: About what?

MS. ANDRAPALLIYAL: I don't think I'm obligated to tell you that.

MR. McGINTY: We just had a break. I think we're going to keep going.

MS. ANDRAPALLIYAL: I'd like to stop, and I don't think that's -- I don't -- yeah, I'd like to stop, please.

MR. McGINTY: Okay. Off the record.

(Recess taken - 1:31 to 1:46 p.m.)

MR. McGINTY: We can go back on the record.

All right. I just want to note for the record that we took about a 15-minute break just now.

BY MR. McGINTY:

Q Ms. Bulls, did you confer with counsel at the break?

A I asked a question.

Q Did you talk to your lawyers?

A Yes.

Q Okay.

MR. McGINTY: Can I ask the court reporter how much time we've been on the record.

(Whereupon, the reporter discloses time spent on the record)

MR. McGINTY: A little less than four hours?

MADAM COURT REPORTER: Yes.

MR. McGINTY: I'll also note for the record that we've been on the record for a little less than four hours.

(Bulls Deposition Exhibit 19 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 19.

MR. McGINTY: Counsel.

(Document tendered to Ms. Andrapalliyal)

BY MR. McGINTY:

Q Do you recognize this document?

A Yes.

Q And what is it?

A A termination letter.

Q Okay. And this is another one that you

signed, right?

A Yes.

Q Okay. And who is the issuing institution -- or the institution that received the termination letter?

A University of Washington.

Q And what's that project number?

A 1R01 TW012904-01.

Q And this is another one that you got in a spreadsheet from your supervisor?

A Yes.

Q Okay. And where are the documents that explain why the grant was terminated?

A The spreadsheet and the request for me to terminate. And this letter right here, sorry.

Q No, that's fine, that's fine.

And, again, this was language -- the language in this letter was provided to you?

A Yes.

Q And you didn't write one word in this letter?

A (Nodding head)

Q Sorry, I didn't hear your answer.

A No. Sorry, no.

(Bulls Deposition Exhibit 20 was marked

for identification.)

BY MR. McGINTY:

Q I'm handing you Exhibit 20. And I'll note that it is big and unwieldy and the pages are not bound. So I'll ask you to be careful with your handling it.

But do you recognize this document?

A Yes. Yes, I do.

Q And what is it?

A NIH Grants Policy Statement.

Q And how are you familiar with it?

A I'm familiar with it because I placed information in it, I use it to advise recipients, I use it to assess compliance, I read it.

Q Assess compliance with what?

A With the policies that are in the policy statement to determine whether or not the recipients are complying with the terms and conditions of the award.

Q Okay. What's the purpose of the document?

A To provide, lay out the grant policy requirements of -- that serve as the terms and conditions of all NIH award administrative requirements.

Q Turn to page Romanette ii. So this

says -- see where it says:

"Is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and condition of NIH grant awards"?

A Yes.

Q And is that a true description of what this document is for?

A It is.

Q Is this the most recent version of this document?

A It is.

Q Okay. Are there any operative amendments to it?

A Can you explain your question.

Q Sure. Has any document been issued that changes the terms of this document?

A The -- there have been Guide Notices that have been issued that we provide to, yes, to the public.

Q To the public?

A Yeah.

Q How many of those have been issued?

A I don't recall.

Q Do you know if it changed the terms?

A They do -- they add to the terms at times.

Q Okay. Let's see, could you turn to page I-53.

Do you see here where it says:

"The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research; and research involving live vertebrate animals"?

A No. Where are you reading from?

Oh, I see it.

Q Okay. You found it?

A Yes, I see it.

Q What does that mean?

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

BY MR. McGINTY:

Q You can answer.

A The public policy requirement is -- this is about making sure that the peer review of the research for humans and an -- human subject, inclusion of gender, members of minority groups.

It basically outlines the public policy requirements that we should point to and consider when we are making awards.

Q What does "inclusion of genders" mean?

MS. ANDRAPALLIYAL: Objection, calls for speculation, assumes facts not in evidence.

BY MR. McGINTY:

Q You can answer.

A "Inclusion of genders" is inclusion of gender, all genders.

Q Okay. All right. What do you mean by "all genders"?

A It means whatever the gender -- whatever is identified as the gender.

Q What does "members of minority groups" mean as used in that section?

MS. ANDRAPALLIYAL: Objection, assumes facts not in evidence, calls for speculation.

BY MR. McGINTY:

Q Well, Ms. Bulls, you helped draft this document, right?

A (Nodding head)

Q Could you answer.

A Yes.

Q And part of your role is to help the ICs

understand what this document means, right?

A That is correct.

Q Is part of your role to help the public understand what this document means?

A That is correct.

Q And so it's part of your regularly occurring duties to interpret this document, isn't it?

A It is.

Q Okay. So what does "members of minority groups" mean here?

MS. ANDRAPALLIYAL: Objection, asked and answered, and the document speaks for itself.

BY MR. McGINTY:

Q You can answer.

A "Members of minority groups" is identified in the Notices of Funding Opportunities. The details of those are typically laid out in the eligibility criteria or the eligibility areas of the Notices of Funding Opportunities. So it would tie back to whatever the program issued in that NOFO and identified in the NOFO.

Q So what's the public policy requirement that they're talking about when they say, "The more significant of the public policy requirements for

the purpose of peer review are those concerning research involving human subjects; members of minority groups"?

Does that refer to the NOFO?

A Yes, because the viewers look at the NOFO, and they review based on the information that's in the Notices of Funding Opportunities. They have their criteria.

Q I see. And the NOFO will have the criteria. How does that relate to the members of minority groups? I guess I'm just not following your answer.

A So if it's a Notice of Funding Opportunity that is specific to a minority health or minority HBCU, the research is linked to that, they will lay out in the NOFO who is eligible to receive the funding and lay out the criteria that they will use for the recipient, or applicant at that time, to be -- to apply for the funding, they lay out that criteria.

And they have to be responsive. And then it goes to peer review for them to review all of how the applicant responded to the Notice of Funding Opportunities. So that's how we look at that from the peer review standpoint.

Q Got it. So this is explaining why you do NOFOs and the way you do it?

A This is explaining the public policy requirements that apply to those NOFOs, and the guidance by which reviewers are looking at as the scientists or the program officials write the NOFOs.

So it's kind of all baked into the Notice of the Funding Opportunity, the purpose of the grant itself. And then we, because before it is an application, once it's an award, then they are bound by the requirements here to follow that.

Q Does anything in this language that we were just talking about suggest that research into transgender or gender diverse health issues would not be a priority for NIH?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A Can you repeat the question.

Q Does anything about the language we've been talking about imply that it's a priority of NIH not to fund research into transgender issues?

A Not at the time that this was issued.

Q Nothing in this language said that?

A Nothing.

Q How about health disparities across racial groups?

MS. ANDRAPALLIYAL: Same objection, calls for speculation.

BY MR. McGINTY:

Q You can answer.

A Yes, same response. The language does not say anything about that in this -- at this time, in the April 2024.

Q Have any of the amendments you just talked about to these policies and procedures changed the NIH priorities for funding of transgender issues?

MS. ANDRAPALLIYAL: Objection to the extent that your question is calling for the provision of deliberative information that hasn't finalized yet.

THE WITNESS: The --

MS. ANDRAPALLIYAL: And instruct the witness not to answer to the extent that the question is asking for that information.

BY MR. McGINTY:

Q I'm asking only about effective policy. I'm asking only about policies that are effective right now, today, that are final.

My question is: Have there been any amendments to this policy statement that would make it so NIH does not have a priority of funding transgender issues?

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

THE WITNESS: No.

BY MR. McGINTY:

Q How about research for racial disparities?

A No.

Q How about research regarding vaccine hesitancy?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Your question is still the same?

BY MR. McGINTY:

Q Yeah. The question is: Are there any effective policies for NIH right now, today, that are final that say that NIH deprioritizes funding for vaccine hesitancy?

A No.

Q Okay. How about research that might benefit institutions in China?

MS. ANDRAPALLIYAL: Same objection, calls

for speculation.

THE WITNESS: Not where there's not a, a foreign interference or nondisclosure requirement or -- but at this time China is on the list of countries of concern.

BY MR. McGINTY:

Q Would you turn to I-73, please. Now what I want to ask you about is this list of, I think it's five things that appears in the top third of the page. It's under a section that's starts on I-72, so if you need to familiarize yourself with any portion, go right ahead.

But my question is, there's these five sections here, could you just read those into the record and tell me what they mean.

MS. ANDRAPALLIYAL: Objections, calls for speculation.

THE WITNESS: So I'm going to read it, but then I also want to respond if that's okay.

BY MR. McGINTY:

Q Sure.

A "Significance, Investigators, Innovation, Approach, Environment." This section was written by, by the experts in the peer review area.

Q Okay. So do you have an understanding of

what this means and how it's used in the grant application and review process?

A I have an overarching understanding of what that means.

Q Okay. I'm just going to be asking for your understanding.

A Yeah.

Q For your understanding, what does "Investigators" mean?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Investigators that are participating on the award that are leading the scientific direction.

BY MR. McGINTY:

Q And it has to do with how qualified the investigators are, right?

A Yes.

MS. ANDRAPALLIYAL: Objection, misstates the -- yeah, misstates the testimony.

BY MR. McGINTY:

Q Does it have to do with how qualified the investigators are who are applying?

A It has to do with their qualifications and their capacity.

Q What makes an investigator qualified?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't feel comfortable answering that because I don't review grants.

BY MR. McGINTY:

Q So you don't know what makes an investigator qualified?

A I know what I would think an investigator is qualified and how they are qualified. But I'm not a scientist, so I wouldn't -- you know, what I might see and someone else might see is two different things. And so I don't want to -- I'm not comfortable with answering that question.

Q Okay. So in your opinion what makes an investigator qualified?

MS. ANDRAPALLIYAL: Objection, calls for speculation, and the witness is not here to testify in her personal capacity.

THE WITNESS: Yeah, I'm not an expert in that.

BY MR. McGINTY:

Q You can answer.

A Yeah, I'm not an expert in --

Q So you don't have an opinion?

A I have an opinion. I'm not comfortable with giving my opinion outside of my official capacity.

Q With all due respect, Ms. Bulls, you are here today to testify, and you've not been instructed not to answer. I'm asking for your opinion.

A It has to be -- I would assume -- so in my opinion, it would be the principal investigator is the person that has the expertise in the scientific area by which they were applying for the grant.

Q And what would give them expertise?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

MR. McGINTY: I'm asking her to explain her opinion.

THE WITNESS: Their background, their qualifications, their experience, publications.

BY MR. McGINTY:

Q If they had background and qualifications and publications in the area that they're applying for a grant for, that would make them more qualified for that grant?

MS. ANDRAPALLIYAL: Objection, calls for speculation, calls for testimony in the witness's

personal capacity which she is not here to do.
BY MR. McGINTY:
Q Is that right?
A Is what right? I'm sorry.
MR. McGINTY: Could you read back the question, please.
(The record was read aloud as follows:
"QUESTION: If they had a background and qualifications and publications in the area that they're applying for a grant for, that would make them more qualified for that grant?")
THE WITNESS: I don't know that it would make them more qualified, because they're -- the grant is -- there's a competition across the board, so they would be in the running to receive a grant.
BY MR. McGINTY:
Q Understood. Thank you.
What does "Environment" mean?
MS. ANDRAPALLIYAL: Objection, calls for speculation.
THE WITNESS: The environment is the -- where the project is going to be taking place, place of performance.
BY MR. McGINTY:

Q And how is that evaluated in the grant application and review process?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know -- so they look at the grant application and they assess whether or not the place of performance is an acceptable place to conduct the research.

BY MR. McGINTY:

Q What would make it acceptable?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Yeah, I can't answer that.

BY MR. McGINTY:

Q Do you have an opinion on what would make it acceptable?

MS. ANDRAPALLIYAL: Objection. The witness is not here to testify in her personal capacity, offer her personal opinions.

THE WITNESS: No, I don't have an opinion.

BY MR. McGINTY:

Q Would you turn to IIA-3.

A IIA-3, you say?

Q No. IIA --

A Oh, 3.

Q -- 3.
A Got you.
Q Could you read the second paragraph that appears on IIA-3.
A "As noted in this section, some requirements may necessitate the submission of a separate document (e.g, human subjects assurance, certification of IRB approval, institutional exemption, civil rights assurance --"
Q I'm going to interrupt you. I meant the second paragraph at the top of the page.
A Oh, I'm sorry.
Q No, you're fine.
A "This chapter addresses the public Policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term 'public policy' indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by the recipients, subrecipients, and contractors, in general, or may relate to the expenditure of Federal funds for

research or other specified activities."

Q So if there were a social, economic, or other objective of distributing NIH funds, I would expect to find it in this Part 4 of this document, right?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Yes.

BY MR. McGINTY:

Q Can you turn to IIA-14. Would you read that paragraph under 4.1.2, Civil Rights Protections, please.

A The entire paragraph?

Q Yes, please.

A I'm going to have to take some water.

Q Please do.

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

conscience protections."

Q That's the end.

A Oh. I thought you said -- I meant the whole, I'm sorry, the whole section.

Q Oh, no, I just meant that first paragraph under that section. I apologize.

A That's okay.

Q So recipients for NIH funding, they're prohibited from discriminating on the basis of sex, right?

A That's correct.

Q And prohibited from discriminating against transgender people also?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion, calls for speculation.

THE WITNESS: That is correct.

BY MR. McGINTY:

Q And they are forbidden from discriminating against gender diverse people, too?

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

THE WITNESS: I would think so.

BY MR. McGINTY:

Q Does this section that we were just

looking at right here, does this imply that NIH has any policy for not funding research into transgender issues?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Not at the time this was issued.

BY MR. McGINTY:

Q So this language doesn't have any implication that NIH does not fund transgender related research?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Not before this. Not before this was issued.

BY MR. McGINTY:

Q Okay. And is there any effective operative amendment to this NIH Policy Manual that would change that so that NIH does have a policy of defunding transgender issues?

A Not at this time. In draft form, but not at this time publicly.

Q Okay. So there's drafts that are being generated that will change that?

MS. ANDRAPALLIYAL: Objection. To the

extent that the question is calling for the privileged and deliberative information that has not been finalized, the witness is instructed not to answer.

BY MR. McGINTY:

Q So right now, today, there is no published NIH policy that says NIH does not fund transgender related issues?

A No.

Q And if I understood your testimony correctly, the only written policy that exists is the form letters that you got in connection with those spreadsheets terminating grants?

MS. ANDRAPALLIYAL: Objection, misstates prior testimony.

THE WITNESS: The letters are not considered policy.

BY MR. McGINTY:

Q The letters aren't policy?

A No, they're not considered policy.

Q So there's no policy that NIH has to defund or to not fund transgender related research?

MS. ANDRAPALLIYAL: Objection, calls for speculation, assumes facts not in evidence.

THE WITNESS: The question you asked

before was whether it was published, anything today, and publicly available. No.

BY MR. McGINTY:

Q Is there a policy that NIH implements but is not published that defunds transgender related research?

A Not at this time.

Q So there's no policy that NIH implements that defunds transgender related research?

A Not at this time.

Q When you say, "this time," what do you mean?

A I'm saying that earlier I spoke to you about the priorities memo. Once that memo is finalized, that will be made publicly available, but it's still in draft form, we're still going through a process.

Q Okay. And is that memo implemented in any way?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion, calls for speculation.

THE WITNESS: No, nothing final is implemented related to the memo.

BY MR. McGINTY:

Q Okay.

A The draft memo.

Q So right now, today, NIH does not have a policy of defunding or not funding transgender related research?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: That is correct.

BY MR. McGINTY:

Q Okay. Now, following this, there's some significant policies having to do with stem cell research and fetal human cells. Is that correct?

A Yes.

MS. ANDRAPALLIYAL: I'm sorry, what page are we on?

MR. McGINTY: Just the following pages, IA-15, IA-16 [sic].

MS. ANDRAPALLIYAL: IIA-15?

MR. McGINTY: Yes, sorry.

BY MR. McGINTY:

Q Are these policies the kind of things -- are these the kind of social, economic, and other policy goals that this Section 4 is about?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Can you repeat. I'm sorry,

I was just --

BY MR. McGINTY:

Q Sure. Let me find it. Okay. When we get to IIA-28 --

A Okay.

Q -- and IIA-29, there's policies about human stem cell research and human fetal tissue research?

A Yes.

Q And earlier in this section we talked about the overriding umbrella section it had, which was, its purpose with to set out the social, economic, and public policy issues surrounding NIH funding. Is that right?

A That is right.

Q Okay. So I'm just asking if these sorts of sections, 4.1.13 and 4.1.14, are examples of those kinds of social, economic, and public policy implications of NIH funding.

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I interpret them to be, yes.

BY MR. McGINTY:

Q Okay. And this references on IIA-28 Executive Order 13505, doesn't it?

A Yes.

Q So when the NIH policies are informed by an Executive Order, it's referenced somewhere, right?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: Yes.

BY MR. McGINTY:

Q Okay.

A Where there is -- correction, where there is an Executive Order, yes.

Q Let's see. I'm looking for 4.1.15. Here we go, "Human Subjects Protections."

Can you summarize this section for me. What are the human subjects protections that NIH implements in this policy manual?

A Making certain that there are assurances and protocols in place to provide protections to participants.

Q And it also requires that human trials include all kinds of people, right?

A I just said, yes.

Q And why is that important?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: It's important to the outcomes of science.

BY MR. McGINTY:

Q And that includes clinically important sex gender differences, doesn't it?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't see it as just one thing. It includes all participants.

BY MR. McGINTY:

Q Which includes sex and gender differences, right?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: It does. I would interpret it to include that.

BY MR. McGINTY:

Q Okay. So is there anything here in this 4.1.15 Section that indicates it is not the policy of NIH to defund or to not fund transgender related research?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: No.

BY MR. McGINTY:

Q Okay. And, in fact, it's actually the opposite, isn't it? This policy actually says that transgender related research is important?

A That is what the policy says at this time, yes.

Q And "at this time," you mean today?

A Yes.

Q So is there anything in this policy anywhere that says that NIH does not fund transgender related research?

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

THE WITNESS: No.

BY MR. McGINTY:

Q And is there anything in any of the effective amendments to this policy that says NIH does not fund or defund transgender related research?

A Publicly, no.

Q Publicly, no?

A No.

Q But NIH is terminating grants on the basis that they fund transgender related research, isn't it?

MS. ANDRAPALLIYAL: Objection, calls for

speculation.

THE WITNESS: Termination letters terminate the grant.

BY MR. McGINTY:

Q On the basis that they are studying transgender related issues?

A And others. And other issues that are -- yeah.

Q Are those other issues anywhere in this policy manual?

A No.

Q Are those other issues anywhere in the effective amendments to this policy memo?

A No.

Q Are you familiar with the 2022 version of this policy memo?

A Yes.

Q Given your job title, it might be an funny question.

Is there anything in that 2022 version that says that NIH has a policy of not funding or defunding transgender related research?

A No.

Q In fact, in that 2022 version, it's also the opposite, the policy is actually to fund that

research, isn't it?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: It doesn't exclude.

BY MR. McGINTY:

Q Doesn't exclude, but research on sex gender minorities is important under that 2022 Version 2, right?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: In the Institutes and Centers where those priorities are, they are able to fund and have been able to fund their research.

BY MR. McGINTY:

Q Have you ever been told not to talk about either of the Executive Orders in your communications about terminating grants?

MS. ANDRAPALLIYAL: Objection. To the extent that -- to the extent the question is seeking attorney-client and deliberative information, I'm instructing the witness not to answer.

BY MR. McGINTY:

Q Can you answer that question?

MS. ANDRAPALLIYAL: Again, to the extent the question is seeking deliberative or

attorney-client information, I instruct the witness not to answer.

BY MR. McGINTY:

Q Without divulging any deliberative or attorney-client privileged information, have you ever been told not to talk about the Executive Orders in your communications about grant termination?

A That would divulge discussions with the Office of General Counsel. And seeking clarity from the funding -- you know, just in seeking clarity between the priorities, we need to know if the priorities, you know, the memo, so.

Q The memo that you are currently drafting?

A The memo that the agency head is drafting.

Q Outside of communications about drafting that memo, has anyone told you not to talk about the EOs when you talk to, for example, the Chief Grants Management Officers?

A No.

MS. ANDRAPALLIYAL: Objection. The question calls for provision of deliberative, attorney-client information, so to the extent that that information is implicated, I would instruct the witness not to answer.

THE WITNESS: During the meetings about staff guidance, no, nobody has told me not to talk about that, but I just don't because it's -- yeah, nobody said not to, though.

BY MR. McGINTY:

Q Have you ever told the Chief Grants Management Officers not to refer to the Executive Orders when they discuss grant terminations with investigators?

A No.

MS. ANDRAPALLIYAL: Objection --

THE WITNESS: No. Sorry.

MS. ANDRAPALLIYAL: Objection to the extent that -- objection. The question is seeking deliberative information so I'd instruct the witness not to answer.

MR. McGINTY: Can you explain your objection to me.

MS. ANDRAPALLIYAL: You're seeking deliberative information that employees are using to make a final policy decision, and so for that reason it's deliberative communications protected by the Daubert process privilege.

MR. McGINTY: I'm seeking a communication that instructs agency behavior, not the information

of the policy.

MS. ANDRAPALLIYAL: I'm not sure I understand the difference.

MR. McGINTY: The difference is one is deliberative and one isn't.

MS. ANDRAPALLIYAL: But any communications that are pre-decisional that go towards that final decision are arguably --

MR. McGINTY: And I'm asking about the final decision not to talk about the EOs.

MS. ANDRAPALLIYAL: Can you repeat the question, please.

MR. McGINTY: Sure.

BY MR. McGINTY:

Q Have you ever told any Grants Management Officers not to talk about the EOs when they discuss grant terminations --

MS. ANDRAPALLIYAL: Objection, vague.

BY MR. McGINTY:

Q -- with the public.

There's no objection on the table. You can answer.

A No.

Q Okay.

A The question is -- I would like to correct

that.

The question has been are we terminating on the basis of the EOs. And the answer is we are looking at the priorities, the agency priorities, and that's what the letter has stated. So that, that's what I'm pointing them back to, the letter and the priorities, not the EOs.

If they asked. If that was a question during a meeting. And the answer was the termination is based on the agency's new priorities as outlined in the termination letters. That's all I provided.

Q The agency priorities are not published in the Grants Management, the Grants Policy Statement, or any amendments to it?

A Correct.

Q The Agency's priorities, as far as you're aware, only exist in form letters that you were given by Rachel Riley?

MS. ANDRAPALLIYAL: Objection, asked and answered.

THE WITNESS: By my supervisor, yes.

BY MR. McGINTY:

Q Okay. And there's no other place where these agency priorities are published or made

available?

MS. ANDRAPALLIYAL: Objection, asked and answered.

THE WITNESS: No.

MR. McGINTY: Okay. I think we're about to move into a new area. It might be time to take a quick five or ten-minute break. Can we go off the record.

(Recess taken - 2:29 to 2:50 p.m.)

MR. McGINTY: We can go back on the record.

BY MR. McGINTY:

Q Now, I know you have a big stack of exhibits right in front of you. And I'm going to ask you to find Exhibit 3 which is the February 28th letter to Dr. Tham.

A Exhibit 3, you said?

Q Oh, did I get the number wrong?

No, not that one. Maybe it's 4.

A Okay.

Q Yeah, 4. Sorry.

A Yeah.

Q Okay. So about a little more than halfway down the page it says here in this letter:

"It is the policy of NIH not to prioritize

these research programs."

Do you see that?

A Yes.

Q Okay. And "these research programs," meaning research programs based on gender identity, right?

A Yes.

Q Now, I just asked you to go through a lot of NIH policies, and your testimony was there is no written final policy of NIH not to prioritize research programs based on gender identity.

That was your testimony, right?

A Yes.

Q So when this letter says it is the policy of NIH not to prioritize these research programs, that's not referring to any written policy, is it?

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

THE WITNESS: I don't know what it was intended to mean because I didn't write it.

BY MR. McGINTY:

Q There is no effective and final NIH policy that you are aware of not to prioritize research programs based on gender identity. Is that right?

A That I know of, no.

Q And in your role as Director of OPERA, would you expect to know about such a policy?

(Reporter requests clarification)

MR. McGINTY: Director of OPERA.

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't -- not necessarily.

BY MR. McGINTY:

Q In your role as Director of OPERA, what kind of policies do you oversee?

A Grants administration policies and grants -- internal policies for our grants managers, which are called the NIH Grants Administration Manuals, which is an internal document that supports the external document which is the NIH Grants Policy Statement.

Q So those are all policies that apply to NIH as a whole?

A Yes.

Q So the policies that you might not be aware of would be policies that would apply to one IC, for example?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know.

BY MR. McGINTY:

Q Do you know of policies within the ICs that you do not oversee?

A I don't know.

Q Okay. And just to be clear, there is no NIH policy not to prioritize research programs based on gender identity that you are aware of?

A That -- that is clear. No, not that I am aware of.

Q Okay.

A Can I ask a point of clarification?

Q Please.

A You are saying NIH policies, and I don't see priorities as something that I would oversee.

Q Sure.

A You know?

Q I understand. I guess my question comes from the part of the sentence where it says, "It is the policy of NIH not to prioritize these research programs." So that's why I'm asking you about the policies of NIH.

A Okay.

Q And you're not aware of any policy of NIH not to prioritize those research programs?

A No, I don't have any (indiscernible).

(Reporter requests clarification)

THE WITNESS: I don't have any insight on it.

BY MR. McGINTY:

Q Okay. So now let's go back to Exhibit 3.

A I don't know if I'll be able to find it now.

(Witness reviews documents)

THE WITNESS: I just saw it. Where did it go? It's running from me. Maybe I'll look closer. I have to re-order.

(Witness reviews documents)

BY MR. McGINTY:

Q I understand the papers get shuffled.

Okay. And we are looking at page 8616 on Exhibit 3, and looking at Section 3(e). The last sentence there, it says:

"Agencies shall take all necessary steps, as permitted by law, to end the Federal funding of gender ideology."

Do you see that?

A Yes.

Q Has NIH, to your knowledge, terminated any grants implementing that sentence?

MS. ANDRAPALLIYAL: Objection, calls for a

legal conclusion, calls for speculation.

THE WITNESS: We terminated it based on the language in the letter.

BY MR. McGINTY:

Q Is it your testimony that the language in the letter had no connection to the sentence that I just read?

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

THE WITNESS: I don't know what the intention was for the two. I don't know.

BY MR. McGINTY:

Q The language in the letter was given to you. Is that right?

A Yes.

Q And you don't know why it was written. Is that right?

A I don't know.

Q Okay. Let's go to Section 3(g) of this same Executive Order.

A Okay.

Q It says:

"Federal funds shall not be used to promote gender ideology. Each agency

shall assess grant conditions and grantee preferences to ensure grants funds do not promote gender ideology."

See that?

A Yes.

Q To your knowledge, has NIH terminated any grants in implementing this section of this Executive Order?

MS. ANDRAPALLIYAL: Objection, calls for a legal conclusion, calls for speculation.

THE WITNESS: To my knowledge, the letter terminates the grant and the language is in the termination letter.

BY MR. McGINTY:

Q Okay. And the reason that the grants were terminated, if I understand your prior testimony correctly, is stated in the letter and it's stated in the spreadsheet that states which grants you are going to terminate. Is that right?

A Yeah, the spreadsheet, remember, I was telling you, it has the categories, like, Y, you know, D, I, that kind of thing.

Q Okay. Are you familiar with the START platform?

A No.

Q Okay. That's not an internal NIH platform for administrative information chain?

MS. ANDRAPALLIYAL: Objection, calls for -- assumes facts not in evidence.

THE WITNESS: What would it be -- I don't under -- is it a part of something I would use for work? I mean --

BY MR. McGINTY:

Q That's my understanding from just googling. I searched START NIH, and that appears to be an internal database. I'm just asking if you are familiar with it?

A I don't know about it, no.

Q Okay.

A I'm trying -- you have me think -- like, NIH like START.

Q S-T-A-R-T.

A Oh, okay. No.

(Bulls Deposition Exhibit 21 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 21. Do you know what that is?

A Oh, gosh.

MS. ANDRAPALLIYAL: Can I have a copy.

(Document tendered to Ms. Andrapalliyal)

THE WITNESS: It's a spreadsheet of all the termin -- it looks like terminations. That's what this says up here, but I'm not familiar with this document.

BY MR. McGINTY:

Q You haven't seen this before?

A Is this the spreadsheet? A spreadsheet that -- we have a master spreadsheet that kind of, I think, has all of the terminations in it. But that's not this -- I don't know if that is this.

Q You don't know by looking at it?

MS. ANDRAPALLIYAL: Objection, asked and answered.

THE WITNESS: The spreadsheet that I have doesn't look like this.

BY MR. McGINTY:

Q What does it look like?

A It has all the information in it, like the grant number, the title, you know, that kind of stuff. I don't know that it has, like -- it has the administering IC.

What does this have? I thought that said program official. It has -- it has a lot of this in it. It does.

Q Okay. Could you go over to "Termination Reason," that column. See the first four rows it says, "gender ideology (EA14168)"? Do you see that?

A This is small.

Q I have a modified version with some columns taken out, it's a bit bigger. Would you like to see that?

A Yes, please. Sorry.

(Bulls Deposition Exhibit 22 was marked for identification.)

BY MR. McGINTY:

Q I'm handing you what's been marked Exhibit 22.

A Yes.

Q And I will represent to you that this is a version of Exhibit 21, and I've taken some columns out so that the information on it is more legible.

A Thank you.

Q But if you ever need to refer back to Exhibit 21 for any reason, let me know. I don't mean to take information away from you, I just want you to be able to see it.

A Exactly.

Q Okay. So the question I just had was, for now, this first four rows, you see where it says

"Termination Reason"?

A Yes.

Q And it says "gender ideology," and then in parenthesis, 14168?

A Yes.

Q Is that the same thing that appears on your internal spreadsheet that you didn't know about?

A Not that I know about.

Q Okay.

A But I will say that there are different spreadsheets that are being maintained, so I don't -- I don't know about all of them. I just know about mine.

Q How do you know there are different spreadsheets that are being maintained?

A Well, because we are actually working with, to give data to HHS. Then we provide data to maintain ourselves so we know when the grant was terminated. And HHS wants to be able to put that information, publicize that information.

So some of this information is made available, like, with the columns, the categories that I was telling you about. So I see the categories which is what determination reason looks

like, but I don't know that I've seen this in my spreadsheet.

Q When you say "this," what do you mean?

A This gender -- so gender ideology, yes. But the EA14168, I don't recall seeing that.

Q You didn't see that. Okay.

MR. McGINTY: Okay. I think we're done.

MADAME COURT REPORTER: May I just ask: would you like to order a copy?

MS. ANDRAPALLIYAL: I would, but we would also like to redirect.

MADAME COURT REPORTER: Oh, sorry.

MS. ANDRAPALLIYAL: But maybe we could -- could we take a break before we do that. Maybe reconvene at 3:30.

(Recess taken - 3:05 to 3:38 p.m.)

MS. ANDRAPALLIYAL: Okay. We're back on the record.

EXAMINATION

BY MS. ANDRAPALLIYAL:

Q Good afternoon, Ms. Bulls.

A Good afternoon.

Q So I'll be asking you just a few questions here today. And let me know if anything is unclear or when you have any questions.

So I'll just start with the Subpoena that was issued that we talked about in Exhibit 1. Do you have the handy?

A Yes.

Q Okay. And will you turn to page 5 of that document. And you see the second half of that page number, "Requests for Production"?

A Yes.

Q Okay. Did you discuss these Requests for Production with counsel?

A No.

Q Okay. Did you receive -- were you told by counsel to collect documents in preparation for these discovery requests?

A Yes.

Q Okay. Is it possible that counsel is collecting documents in other ways apart from asking you to collect documents?

MR. McGINTY: Objection, calls for speculation.

THE WITNESS: It is possible.

BY MS. ANDRAPALLIYAL:

Q Okay. Are you aware of whether counsel is collecting documents in other ways?

A I don't know.

Q Okay. I'll turn to -- and I'm sorry, I don't have the exhibit number handy, but the one, DEI Staff Guidance.

MR. McGINTY: Which one?

MS. ANDRAPALLIYAL: The third one.

(Reporter requests clarification)

MS. ANDRAPALLIYAL: DEI Staff Guidance.

MR. McGINTY: The one dated March 25?

MS. ANDRAPALLIYAL: No, I guess, the first one, please.

MR. McGINTY: The first one, so the one dated February 12th.

MS. ANDRAPALLIYAL: Okay, yes.

MR. McGINTY: So that would be Exhibit 8.

MS. ANDRAPALLIYAL: Exhibit 8, okay.

BY MS. ANDRAPALLIYAL:

Q Do you have Exhibit 8 handy, Ms. Bulls?

A Yes.

Q You have it?

A Yes.

Q Okay, great.

Now, what, in your understanding, was the basis for issuing this; in other words, what policies were the basis for issuing this Staff Guidance, to your knowledge?

A There wasn't a policy that was issued. It was the temporary restraining orders that were issued that caused us to develop this guidance. There was a funding pause.

Q Mm-hmm.

A And the funding pause was in place, and we were trying to figure out, you know, just make sure that folks understood that the -- given, you know, the recent court -- it says, "...given the recent court orders, this cannot be a factor in IC funding decisions at this time."

So we're trying to talk about the fact that leadership is going to be looking over agency priorities.

Q Okay. Okay.

MS. ANDRAPALLIYAL: Okay. And then can we go to -- and what was the second version, which exhibit was that?

MR. McGINTY: The one dated February 13th.

MS. FRAAS: 7, I believe.

MR. McGINTY: Yeah, the one dated after the one that said follow court order, it says don't follow court orders. And that's February 13 and that's Exhibit 7.

BY MS. ANDRAPALLIYAL:

Q Do you have that one handy?
A Yes, I do.
Q Okay. And, to your knowledge, what were -- what, if any, policies or priorities were the basis for this guidance?
A There were no policies. There were no priorities for the guidance.
Q Okay. When you say there were no priorities, do you mean there were no final priorities, or something else?
A Final priorities. I issued this based on the Secretarial directive related to DEI funding.
Q Okay.
A That was just to say that, that the Secretary had issued a memo, or a Secretarial directive.
Q Okay.
A So it wasn't agency priorities, but it was a Secretarial directive.
Q Okay. So it was a Secretarial directive. So when you say -- when you contrast with an agency priority, what do you mean by that?
A It means, for me, that there was a directive coming from HHS Office of the Secretary that was issued to the NIH and the other operatives.

Q So by "agency," do you mean NIH? Are you contrasting NIH with HHS when you are distinguishing between --

A Yeah, I am.

Q -- Secretarial directive and agency priorities directive?

A Yeah.

Q Okay. Well, let me switch gears a little bit.

If we can go to Exhibit -- go to Exhibit 4 which, I believe, is the December 28th termination. Give me one second.

So looking at that document, but also looking at the several other exhibits that we've discussed earlier in this deposition regarding other grant terminations, is it correct to say that your prior testimony identified three documents that, in your view, explained the terminations? And by those three documents, I mean an e-mail you received, spreadsheets you received, and a template letter.

A Yes.

Q Is that correct?

A That is correct.

Q Okay. Do you know if there are other documents out that NIH has produced that would

explain these terminations but that you did not receive?

A I do not know.

Q Okay. Is it possible?

A It is possible.

Q Now, can you remind us of your title again.

A The Director of the Office of Policy for Extramural Research Administration.

Q And what's the title of the person you report to?

A The Deputy Director for Extramural Research.

Q And who does that person report to?

A The Principal Deputy of Extramural Research.

(Reporter requests clarification)

THE WITNESS: Extramural.

And, I believe, the person I reported to, the Principal Director and Director, so.

BY MS. ANDRAPALLIYAL:

Q And the Principal Deputy is one title, and then above that is the Director. Is that correct?

A That's correct.

Q Okay. And who does the Director report

to?

A Secretary.

Q Secretary of HHS?

A HHS.

Q Okay. Now, are you involved in the discussion of what should be agency priorities in funding research?

A No.

Q No? Okay. Who would be involved in those discussions?

A It would be the Deputy Director for Extramural Research, the Principal Deputy, and the Director of the Agency along with all of the Institute and Centers Directors.

Q Okay. And who actually sets agency priorities for funding, for funding research?

A The Director along with the IC Directors.

Q Okay. Now, are you aware of whether the Acting Director has issued funding priorities?

A I'm not aware.

Q Are you aware of draft priorities?

A I am aware of draft priorities.

Q Of draft priorities that are currently being developed?

A I'm aware -- I saw a draft document, but I

don't know if it's still under development. I'm not -- I don't have any insight. I just know that I saw a draft document, definitely, yes.

Q Do you know if any draft priorities have been finalized?

A I don't know.

Q Is it possible that they have and you don't know?

A It is possible.

Q Turning back to Exhibit 4, I know I'm jumping around a little bit, I do apologize.

But turning back to Exhibit 4 to the grant termination letter, at one point counsel for Plaintiff asked you to compare the language in that letter to the language in Exhibit 3, which is the Executive Order 14168. Is that correct?

A Yes.

Q Okay. And specifically, I believe, asked you to compare the language in that letter to Section 2 of the Executive Order. Is that correct?

A Yes.

Q Okay. Section 2 on page 1, at the bottom of page 1.

A Mm-hmm, yes.

Q Okay. Now, do you have any basis, any

official basis, to know whether the language in that termination letter was included because of the Executive Order?

A No.

Q Do you have any reason to believe or -- you said at one point that the language looked similar.

What was the basis for that, for that statement?

A Just me looking at it today, yeah.

Q Okay. Did anybody tell you that the letter was based on the Executive Order?

A No.

Q Do you have reason to believe that it was, that the letter was based on the Executive Order?

A I don't know.

Q Okay. The letter in Exhibit 4 says that, that this award no longer effectuates agency priorities. Is that correct?

A Yes.

Q Okay. And do you have reason to believe that those agency priorities are based on Executive Order 14168?

A Can you restate.

Q Sure. Do you have reason to believe, in

your official capacity, that the language in the letter saying that this award no longer effectuates the agency priorities was based on Executive Order 14168?

A No.

Q Okay. Let me switch gears again and let me go back to that third version of the Staff Guidance in the record, the March 25th document.

Do you have that handy?

A Exhibit?

MR. McGINTY: For the record, I believe this is Exhibit 6.

BY MS. ANDRAPALLIYAL:

Q Exhibit 6.

A Okay.

Q Okay. Thank you.

Now, Ms. Bulls, is that a final document that you have there as Exhibit 6?

A No, it's not intended to be final.

Q Okay. Is there a watermark on that document?

A Yes.

Q What does the watermark say?

A "Confidential."

Q Is there a header on that document?

A Yes.

Q What does the header say?

A "Internal: Not for Distribution Outside of the Government."

Q Do you know why that watermark and that header was included on this document?

A Yes.

Q Why?

A Because people were sending the document out to places where it's being posted publicly.

Q And why is it a problem that this document was being posted publicly?

A Because, one, it was a draft document, and, two, it was an internal document, Guidance for Staff, and ...

Q So when you say it was a draft document, was it -- was it subject to change?

A Yes.

Q When you sent it out, what was the purpose of sending this kind of document out?

A I sent it out and asked for folks to -- because they had a lot of questions, and so I asked them to take a look at the document to see if the updated version of the document answered their questions.

Q And what are the problems that arise if a draft document is posted publicly?

A People have information that is not final, it's internal, and it's still going through vetting processes. So it gives the pre-- what do you -- I mean it's like pre-information that's not available, not even final, within the agency.

Q And is it possible that there are inaccuracies in a draft document like that when it hasn't been finalized?

A Yes, because it still has to go through approval within the management and leadership levels and be approved, or at least reviewed by OGC.

Q And is it possible that that kind of document would be materially changed before it's finalized?

MR. McGINTY: Objection, leading.

THE WITNESS: The document has changed over time, and it's very different than where it started. And, yeah, it's not the same document.

BY MS. ANDRAPALLIYAL:

Q So it has changed -- sorry.

Are you saying that it has changed over time?

A Yes.

Q Okay. And could it change further over time?

A It will.

Q Okay.

MS. ANDRAPALLIYAL: I'm going to jump around again, and we might need an exhibit number again here. The reinstatement document?

Do you have that exhibit number, Counsel?

MR. McGINTY: I believe that's Exhibit 10.

BY MS. ANDRAPALLIYAL:

Q Do you have that handy, Ms. Bulls?

A I'm getting at it. We were doing fine before the grants policy.

(Whereupon, laughter)

BY MS. ANDRAPALLIYAL:

Q Okay. Do you have a copy of that now, Ms. Bulls?

A Yes, I do.

Q Okay, great. Could you turn to page 5 of that document, please.

(Reporter requests clarification)

MS. ANDRAPALLIYAL: Yes, page 5 of this reinstatement document.

BY MS. ANDRAPALLIYAL:

Q Okay. And could you remind us which part

of Section IV has the language that you drafted?

A This:

"Revised Award: This grant has been restored and the termination clause rescinded effective immediately. The grant will continue under the original no cost extension."

Q Okay. Now, below that there is -- sorry, at the very end of that page there's a statement that says:

"The previous terms and conditions of award remain in effect."

Do you see that language down at the bottom?

A Yes.

Q Now, is it part of your job responsibilities to interpret these kinds of Revised Notices of Award?

A I never see them.

Q You never see them? Okay.

A No.

Q Who is in charge of administering them?

A The Institute and Centers, so the Chief Grants Management Officer is responsible for making sure that the terms are correct.

Q Okay. So in your duties do you typically come across these Revised Notices of Award?

A No.

Q No? Okay.

Do you have reason to believe that the language beginning on page, at the bottom of page 5 in some way invalidates the reinstatement of the grant?

MR. McGINTY: Objection, leading, lack of foundation.

BY MS. ANDRAPALLIYAL:

Q What does this Notice of Award do? What does this document do?

MR. McGINTY: Objection, lack of foundation.

BY MS. ANDRAPALLIYAL:

Q Do you know what this document does?

A The document communicates the terms and conditions to the recipient.

Q Okay. A Notice of Award, what is a Notice of Award?

A It's a funding instrument.

Q Okay. And so, do you understand what this, what this Notice of Award is doing?

A Yes.

Q What is it doing?

A It is giving funding information from the Institute and Center to the recipient.

Q Okay.

A And are you talking about this particular award, or all? Just --

Q I'm talking about this particular award.

A This particular award is communicating that the grant has been restored and that the termination clause is rescinded.

Q Okay.

A This is the first part. Because there's a second part, too, so. That's the only one I know about.

Q Okay. And by "second part," what do you mean by second part?

A So when Institutions and Centers issue awards, they issue the original award and then they issue revisions on top of that.

Q Okay.

A So the top revision was the latest revision as of the issue date of 3/27.

Q Okay. And so when you drafted this language regarding the revised award, what was the intent of that language?

A To restore the grant and to rescind the termination.

Q Okay. And did you mean to conditionally restore the grant?

A No.

Q Okay. Did this language intend to subject the reinstatement to, to the language that follows regarding, yeah, the start at the top of page 6?

A No, my language was to restore the grant, which is what I sent to the Chief GMO.

Q Okay.

A The other language looks like it was adding money back to the grant, which I had -- that was just an action from the Chief GMO to restore funding back to the grant.

Q I see. You're talking about the second revised --

A -- revision, yes.

(Simultaneous speaking)

BY MS. ANDRAPALLIYAL:

Q -- statement. I see.

A Yeah, which was separate from the first one.

Q I see, okay. And then can we move to the manual, that big stack at the bottom. So can we

just go to the introduction on page ii.

A Yes.

Q What is your understanding of the point of this, of this manual? What is the purpose for this manual?

A It's to provide NIH recipients with the policy requirements and lay out the standard terms and conditions of the award.

Q So when you say that it's meant for NIH recipients, does that mean it's for people who have already received, or institutions that have already received NIH grant funding?

A Yes.

Q Okay. How often is this manual updated, in your experience?

A It's typically updated annually.

Q Annually?

A Yes.

Q Okay. And so when was this document most recently updated?

A It was updated April 2024. Well, that's the publication date.

Q And, in your experience, has NIH issued new funding priorities or policies outside of this policy statement or initially without modifying this

policy statement?

A Yeah, funding priorities are typically outside of it. And they're housed on the websites of the Institutes and Centers.

Q Okay.

A We usually just issue a Guide Notice to talk about, you know, what the public policies are, legislative mandates, but we don't get into the funding, aside from the CRs. We have to issue a CR Notice.

Q Okay. And what are Guide Notices? You used that term earlier.

A Yeah, Guide Notices communicate NIH policies in the interim, between the time that the policy statement is updated, because policies change before the policy statement is revised. So we use that as an instrument to communicate the policies, policy changes, that might impact the end grants policy statement.

Q Do you know if there are new Guide Notices being developed at this time based on any new agency priorities for policies?

A I don't know.

Q Okay. Ms. Bulls, I'm done with my questions. Thank you so much for your time.

A Thank you.

MR. McGINTY: I will have some follow-ups. Take a five-minute break?

(Recess taken - 4:08 to 4:16 p.m.)

MR. McGINTY: Let's go back on the record.

FURTHER EXAMINATION

BY MR. McGINTY:

Q Thank you, Ms. Bulls, for hanging in there. I think we're almost done.

A Okay.

Q You were asked about Exhibit 1, the Subpoena Duces Tecum that was sent to you.

A Yes.

Q Do you recall just now you were asked about that?

A Yes.

Q And you were asked if counsel directed you to gather those documents. Is that right?

MS. ANDRAPALLIYAL: Objection, misstates prior testimony.

MR. McGINTY: Would you read that back.

(The record was read aloud as follows:

"QUESTION: And you were asked if counsel directed you to gather those documents. Is that right?")

MR. McGINTY: If you go back up to the redirect, and I believe the question was about counsel's representation to Ms. Bulls about Exhibit 1.

(The record was read aloud as follows:

"QUESTION: So I'll be asking you just a few questions here today. And let me know if anything is unclear or when you have any questions.

"So I'll just start with the Subpoena that was issued that we talked about in Exhibit 1. Do you have that handy?

"ANSWER: Yes.

"QUESTION: Okay. And will you turn to page 5 of that document. And you see the second half of that page is numbered 'Requests for Production'?

"ANSWER: Yes.

"QUESTION: Okay. Did you discuss these Requests for Production with counsel?

"ANSWER: No.

"QUESTION: Okay. Did you receive -- were you told by counsel to collect documents in preparation for these discovery requests?

"ANSWER: Yes.
"QUESTION: Okay. Is it possible that counsel is collecting documents in other ways apart from asking you to collect documents? ")
MADAM COURT REPORTER: Is that what you wanted?
MR. McGINTY: Yes, thank you.
BY MR. McGINTY:
Q So you were asked if counsel instructed you to collect documents in response to those requests, right?
A Yes.
Q And you did collect those documents, right?
A Yes.
Q And other than your CV, are you aware of any of those documents having been provided to Plaintiff's counsel today?
A I don't know.
Q And you've been here all day. Did you see counsel give those documents to us?
A No.
Q Let's see. When you were asked about Exhibit 8, which is the February 12th Staff

Guidance -- if you could pull that up, that would be great.

Now, this was from Dr. Lauer and from you. Is that right?

A That is correct.

Q And Dr. Lauer resigned the next day, right?

A I don't remember.

Q You don't remember. Did Dr. Lauer resign?

A Yes, he did. He retired.

Q Do you know if it had any connection with this Exhibit 8?

A I'm sorry?

Q Do you know if his retirement had any connection with this Exhibit 8?

A No.

Q Okay. When you were asked about Exhibit 7, if I remember correctly, you said that Exhibit 7 was in response to a Secretarial directive. Did I understand that right?

A Yes.

Q Was that Secretarial directive written down?

A Yeah, it's in the document from the department. It was attached.

Q I see. It is this February 10th document here?

A Yes.

Q Okay. And that had to do with DEI funding?

A Yes.

Q Is it common for those kinds of directives to come from HSS?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know.

BY MR. McGINTY:

Q Okay. I'm going to ask a bit, a few more questions about Exhibit 4, the February 28th letter.

And you were asked if you knew whether or not there were other documents other than the e-mail, the spreadsheet, and the template letter that explained terminations like what we see on this Exhibit 4.

Do you remember that?

A Yes, I do.

Q And, as I recall your testimony, you said you didn't know if there were other documents that might exist.

A I don't know if there are other documents.

Q If you wanted to find that out, who would you ask?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: If I wanted to find out who would I ask? My supervisor.

BY MR. McGINTY:

Q Okay. Who, right now, is who?

A Jon Lorsch.

Q Jon Lorsch.

A But at the time I think it was Liza Bundesen.

Q Liza Bundesen might know?

A I don't know.

Q Can you think of anybody else who might know whether or not other documents exist?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: No, I don't know. I don't.

BY MR. McGINTY:

Q How about Rachel Riley?

A I don't know.

Q Okay. Just confirming your testimony, you got this template language word for word, right?

A Yes.

Q You didn't write one word in this?
A No.
Q And there's several letters like this. I think you testified somewhere over five hundred and less than a thousand for grants that you terminated with those kind of template letters. Is that right?
A Yes.
Q Is that common?
MS. ANDRAPALLIYAL: Objection, calls for speculation.
THE WITNESS: Is -- is what common?
BY MR. McGINTY:
Q Have you ever, before January 20th, 2025, put your name on a letter like this without having written a single word of it?
MS. ANDRAPALLIYAL: Objection, beyond the scope of redirect.
BY MR. McGINTY:
Q You can answer.
A No.
Q And it's your testimony that you don't know why any of this language was included, right?
MS. ANDRAPALLIYAL: Objection, misstates prior testimony.
BY MR. McGINTY:

Q Do you know why any of this language is included?

A No.

Q Before January 20th, 2025, did you put your name on a letter when you didn't know why any of the words were included in it?

MS. ANDRAPALLIYAL: Objection, argumentative.

THE WITNESS: Not that I can recall.

BY MR. McGINTY:

Q Is that something you might remember?

A I don't know.

Q You were asked if you were regularly involved in discussions of what agency priorities should be, and I think you said: Deputy Director, Principal Director, the Director of the agency, and the Institute Directors. Is that right?

A Yes.

Q Okay. And can you name those people for me?

A The acting leader -- or, well, from when these letters were written? Is that what you mean? Yes.

Q I mean everybody from the first letter, which I understanded is February 28, 2025, to the

most recent, which I think is March 27th.

Who are all the people in that time frame who would be involved in discussions about what agency priorities should be?

A I don't know. I don't know -- I know who the people -- I know the people that were in the positions, but I don't know if they were discussing agency priorities. Because we were talking about funding priorities, that's what I was saying to counsel.

Q Oh, okay. In funding priorities, then.

A Funding priorities.

Q Then funding priorities, then.

A During the time that this letter was issued, it would have been Liza, maybe, and Dr. Memoli. I don't know of anyone else except for the IC directors that probably were --

Q Okay. And how many IC directors are there?

A There are, I want to say, 20 -- well, there's 27 different Institute and Centers, but there's 24 ICs that administer funds. So I'm going to just talk about the 24 that I know. And I'm not sure the CSR has an IC director. Yeah, so, yes, 24.

Q Okay. If I am understanding you

correctly, the people who might be involved in those discussions of what agency funding priorities should be would be Liza Bundesen, Dr. Memoli, and then the 24 IC directors?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

MR. McGINTY: Following up on the question you asked.

THE WITNESS: I'm sorry?

BY MR. McGINTY:

Q I'm following up on a question that counsel asked.

A Oh, okay.

Q She asked you who are the people who would be involved in agency priorities for funding, and you said Deputy Director, the Principal Director, the Director of the agency, and Institute Directors. I'm just making sure I have a full list of who that is.

A So you want the names of the individuals or -- I don't understand the question.

Q If I get the names of the individuals that would be great.

A The names -- I don't know the names of all of them, so it's just Liza and Matt. Matt from this

letter.

(Reporter requests clarification)

THE WITNESS: Matt, M-a-t-t, Matthew Memoli.

BY MR. McGINTY:

Q Plus the 24 IC directors?

A Yes.

Q And I think you said the acting director generally does funding priorities.

Are funding priorities generally written down somewhere?

A They're on the -- it's not the acting director, it's the Institute and Centers. And their funding priorities and funding strategies are out on their individual websites.

Q Are you generally familiar with those?

A No. I'm familiar with just the overarching strategy, which is to push, because they have different strategies, you send the recipients back to the various Institute and Centers to look at those.

Q Okay. And in this instance with respect to this February 28th letter we're looking at and the other termination letters that reference the policy of NIH not to prioritize certain research

programs, that didn't come from the Institute and Centers, did it?

A I don't know. I don't know.

Q Were they -- is any language like this on any of the Institute and Centers websites?

A Not that I know of.

Q And earlier it was your testimony that this was sent to -- or sent from someone at HHS. So Rachel Riley?

A This particular language and e-mail, yes.

Q The language that we're looking at in Exhibit 4?

A Yes.

Q Do you have any reason to believe that the Institute and Centers sent that language up to HHS and it was distributed back down?

A I don't know.

Q How many Institutes and Centers have grants that were terminated with these kinds of form letters?

A Many, if not --

Q All of them?

A -- most.

Q Sorry, I spoke over you. Can you say that again?

A Many, if -- yeah, many.

Q Is it all of them?

A By now it might be. I don't know. I -- I honestly just don't know. But I believe that all of them have been impacted at this point.

Q So it stands to reason that this is not a funding priority that's coming from the individual Institutes and Centers, doesn't it?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know.

BY MR. McGINTY:

Q You were also asked if you have any official basis to know whether the language in these template letters relates in any way to the Executive Orders. Do you recall that testimony?

A Yes.

Q And you testified you don't have any reason to believe that or to know that on your official basis?

A That is correct.

Q If you wanted to figure that out, who would you ask?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I would ask my supervisor.

BY MR. McGINTY:

Q Which in February 28 was Liza Bundesen?

A Correct.

Q Can you think of anybody else who might know?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I can't.

BY MR. McGINTY:

Q Is it possible that Rachel Riley knows?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: I don't know. It's possible. I don't know.

BY MR. McGINTY:

Q You were asked about this March 25th Guidance, Exhibit 6.

And your testimony was it's still subject to change, right?

A Yes.

Q Has this Guidance been relied on by any Institute or Center to take any action?

A I don't know.

Q If you wanted to know that, who would you

ask?

A The Institute and Center.

Q You have to ask each Institute and Center directly?

A I would.

Q And you testified about Exhibit 10 which was the March 27th Notice of Award.

A Yes.

Q And I think your testimony here was that it's not within your usual job duties to interpret these kinds of Notices of Award. Is that right?

A Yes. No, I don't usually interpret these Notices of Awards. I don't -- my testimony, what I recall is that I said I don't normally see them so I wouldn't interpret them.

Q You don't normally see them, let alone interpret them?

A Right.

Q Fair enough. Earlier when you were looking at page 5 and page 6, your testimony was it looked to you, maybe on the basis of just a lay person's understanding, that this language under termination and transgender issues may have been included by mistake.

Do you recall that testimony?

A I do recall that testimony, yeah.

Q If I wanted to get to the bottom of that, who would I need to ask?

A You would need to ask the Institute or Center, so Maggie. Margaret Young.

Q Margaret or Maggie Young?

A Yes.

Q How is Maggie spelled?

A M-A-G-G-I-E.

Q Great. Do you know if NIH has ever made a promise not to terminate this grant in the future?

MS. ANDRAPALLIYAL: Objection, calls for speculation.

THE WITNESS: No, I don't know that.

MR. McGINTY: Okay. Nothing further.

MS. ANDRAPALLIYAL: We're good. Thank you.

MR. McGINTY: Oh, yeah. We do need the rough transcript, I'll put that on the record.

MADAM COURT REPORTER: And you're ordering the original --

MR. McGINTY: We're ordering the original and we'll probably expedite it.

MADAM COURT REPORTER: Okay.

And may I ask, are you ordering a copy,

and when do you need it? Do you need a rough draft, too?

MS. ANDRAPALLIYAL: Yes, please. Yeah, and on the same time frame, I guess, for both.

(Whereupon, at 4:38 p.m. the deposition of MICHELLE G. BULLS was concluded.)

ACKNOWLEDGMENT OF DEPONENT

I, MICHELLE G. BULLS, do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

I, Bess A. Avery, Registered Merit Reporter, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 7th day of April 2025.

My commission expires:
November 14, 2028

_____

/s/BESS A. AVERY
NOTARY PUBLIC IN AND FOR THE
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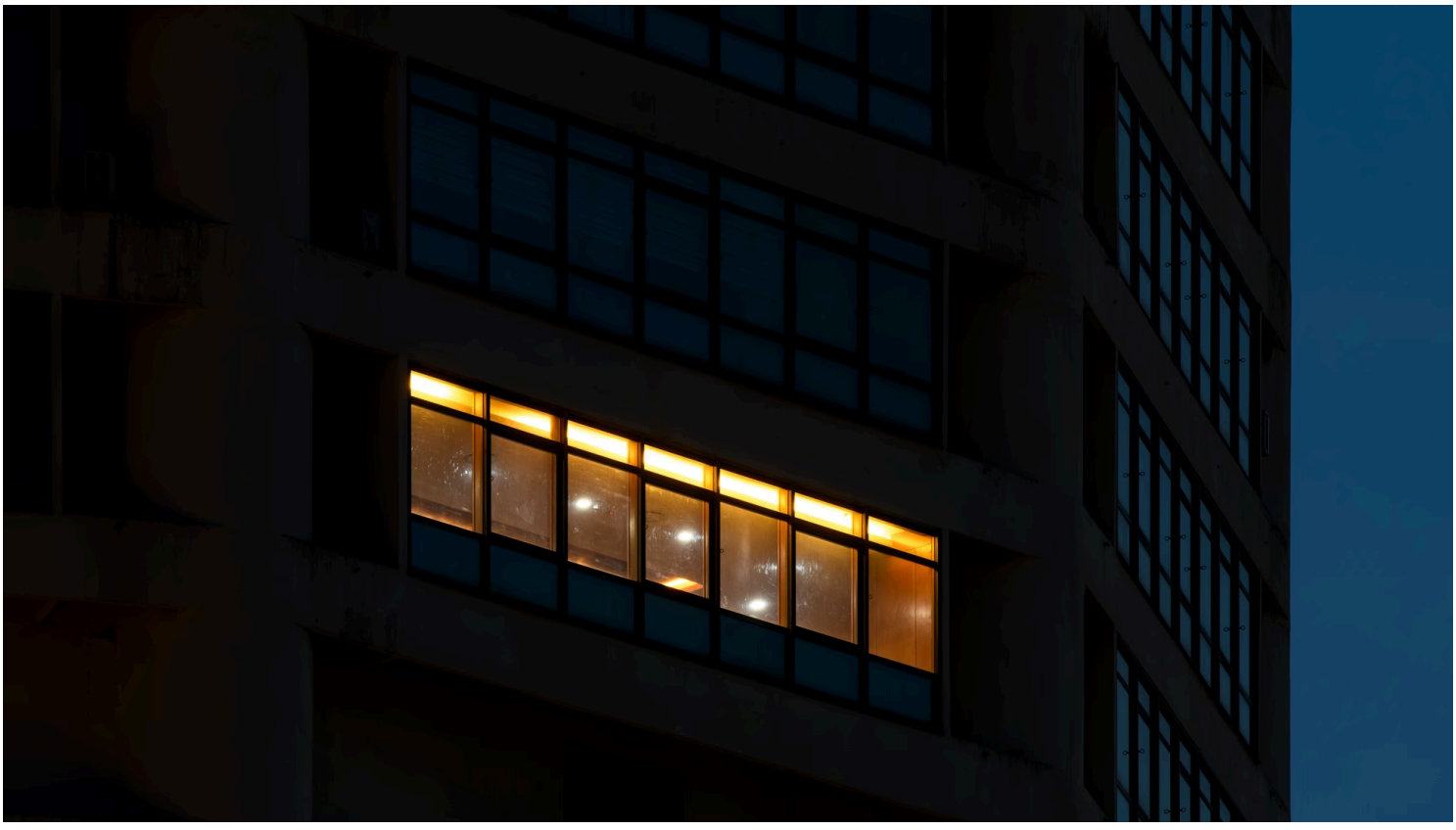
EXHIBIT 42

HEALTH

Inside the Collapse at the NIH

Administration officials pressured the NIH to avoid clear advice from the agency's own lawyers to restart grant funding now.

By Katherine J. Wu



Jordan Lye / Getty

FEBRUARY 27, 2025

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Updated at 5:26 p.m. on February 28, 2025.

If you have tips about the Trump administration's efforts to remake American science, you can contact Katherine on Signal at @katherinejwu.12.

For decades, the National Institutes of Health has had one core function: support health research in the United States. But for the past month, the agency has been doing very little of that, despite multiple separate orders from multiple federal judges blocking the Trump administration's freeze on federal funding. For weeks on end, as other parts of the government have restarted funding, officials at the Department of Health and Human Services, which oversees the NIH, have pressed staff at the agency to ignore court orders, according to nearly a dozen former and current NIH officials I spoke with. Even advice from NIH lawyers to resume business as usual was dismissed by the agency's acting director, those officials said. When NIH officials have fought back, they have been told to heed the administration's wishes—or, in some cases, have simply been pushed out.

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The lights at the NIH are on; staff are at their desks. But since late January, the agency has issued only a fraction of its usual awards—many in haphazard spurts, as officials rushed grants through the pipeline in whatever limited windows they could manage. As of this week, some of the agency's 27 institutes and centers are still issuing no new grants at all, one NIH official told me. Grant-management officers, who sign their

name to awards, are too afraid, the official said, that violating the president's wishes will mean losing their livelihood. (Most of the officials I spoke with requested anonymity, out of fear for their job at the agency, or—for those who have left—further professional consequences.)

Read: The erasing of American science

NIH lawyers have told officials at the agency that to comply with court orders, they must restart grant awards and payments. But HHS officials have handed down messages too, several current and former NIH officials told me: *Hold off. Maintain the pause on grants.* And the NIH's acting director, Matthew Memoli, who until January was a relatively low-ranking flu researcher at the agency, has instructed leadership to stick to what HHS says. (After this story was published, an NIH spokesperson wrote to *The Atlantic* defending Memoli's actions, arguing that his "priority is to ensure that NIH is complying with the administration's directives and related court orders so that NIH research and funding can fully resume." HHS did not respond to a request for comment.)

NIH officials are used to following cues from their director and from HHS. But they were also used to their own sense of the NIH's mission—to advance the health of the American people—being aligned with their leaders'. For weeks now, though, they have been operating under an administration ready to dismantle their agency's normal operations, and to flout court orders to achieve its own ends.

As the freeze wore on, one former NIH official told me, some people at the agency recalled a mantra that Lawrence Tabak, the NIH's longtime principal

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Case 1:25-cv-10814-BEM Document 1-27 Filed 04/14/25 Page 4 of 12

deputy director, often repeated to colleagues: *As civil servants, your role is not to call the policies, but to implement them. That is your duty, as long as you're not doing something illegal or immoral.* The NIH's expert staff might have their own ideas about how to allocate the agency's funds, but if political leaders chose to pour money into a pet project, that was the leaders' right. This time, though, many at the NIH have started wondering if, in implementing the policies they were told to, they were crossing Tabak's line. Over and over, the former NIH official told me, "We were asking ourselves: *Are we there yet?*"


The Fleeting Magic of Scholastic Book Fairs
MARINA KOREN

WITHOUT THE ABILITY to issue research grants, the NIH effectively had its gas line cut. The agency employs thousands of in-house scientists, but a good 80 to 85 percent of its $47 billion budget funds outside research. Each year, researchers across the country submit grant proposals that panels of experts scrutinize over the course of months, until they agree on which are most promising and scientifically sound. The NIH funds more than 60,000 of those proposals annually, supporting more than 300,000 scientists at more than 2,500 institutions, spread across every state. This system backed the creation of mRNA-based COVID vaccines and the gene-editing technology CRISPR; it supported 99 percent of the drugs approved in the U.S. from 2010 to 2019. The agency has had a hand in "nearly all of our major medical breakthroughs over the past several decades," Taison Bell, a critical-care specialist at UVA Health, told me.

That system ground to a halt by late January, after the Trump administration paused communications across HHS on January 21, and a memo released from the Office of Management and Budget just days later froze funding from federal agencies. The NIH stopped issuing new awards and began withholding funds from grants that had already been awarded—money that researchers had budgeted to pay staff, run experiments, and monitor study participants, including, in some cases, critically ill patients enrolled in drug trials.

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Several of the agency's top officials immediately sought advice from Tabak, who served as interim director from December 2021 to November 2023, and had long been a liaison between the agency and HHS. But Tabak openly admitted, several officials told me, that his power in this moment was limited. Although he had been the obvious choice to act as the NIH's interim leader after Monica Bertagnolli, the most recent director, stepped down, the Trump administration hadn't tapped him for the position. In fact, several officials said, the administration had ceased communicating with Tabak altogether. (Tabak declined to comment for this story.)

The role of acting director had instead gone to Memoli, who had no experience overseeing awards of external grants or running a large agency. But, officials said, Memoli had expressed beliefs that seemed to align with the administration's. In 2021, he had called COVID vaccine mandates "extraordinarily problematic" in an email to Anthony Fauci (then director of the NIH's National Institute of Allergy and Infectious Diseases) and reportedly refused the shot himself; last spring, Jay Bhattacharya, Donald Trump's nominee to lead the NIH, praised Memoli on social media as "a brave man who stood up when it was hard." And last year, Memoli had been deemed noncompliant with an internal review, two officials said, after he submitted a DEI statement calling the term "offensive and demeaning."

Read: A new kind of crisis for American universities

From the moment of his appointment, Memoli became, as far as other NIH staff could tell, "the only person the department or the White House was speaking directly to" on a regular basis, one former official said. And the message he passed along to the rest of the agency was clear: All NIH grants were to remain on pause.

That position was at odds with a growing number of court orders that directed the federal government to resume distributing federal funds. Some of those orders included painstaking, insistent language usually reserved for defendants who seem unlikely to comply, Samuel Bagenstos, who until December served as general counsel to HHS, told me. In written correspondence with senior NIH leadership in early February, current HHS lawyers, too, interpreted the court's instructions

unambiguously: "All stop work orders or pauses should be lifted so contract or grant work can continue" and contractors and grantees could be paid. In other words, put everything back the way it was.

Government lawyers aren't the final arbiters on what's legal. But the National Science Foundation, for instance, unfroze its funding on February 2. And the independent lawyers I spoke with agreed with what HHS counsel advised. The continuation of the NIH freeze "is unambiguously unlawful," David Super, an administrative law expert at Yale University and Georgetown University, told me. The money that Congress appropriates to federal agencies each year is intended to be spent. "If they're holding it back for policy reasons," Super said, "they're violating the law."

At a meeting on February 6, several of the agency's institute and center directors demanded that Memoli explain the NIH's continued freeze. David Lankford, the NIH's top lawyer, said that the position of the general counsel's office aligned with that of the courts: Grants should be "awarded as intended."

But Memoli called for patience, officials with knowledge of the meeting told me. He was waiting for one thing in particular to restart grant funding: He had tasked Michael Lauer, the deputy director of the NIH's Office of Extramural Research, which oversees grants, to draft a formal plan to make the agency's funding practices consistent with Trump's executive orders on gender, DEI, foreign aid, and environmental justice. (Lauer declined to comment for this story.)

Squaring those orders with the NIH's mission, though, wasn't straightforward. One sticking point, officials said, was funding for research into health disparities: If the administration's definition of DEI included studies that acknowledged that many diseases disproportionately affect Americans from underrepresented backgrounds, complying with Trump's orders could mean ignoring important health trends—and broad cuts in funding across many sectors of research. Cancer, for instance, disproportionately affects and kills Black Americans; men who have sex with men are the population most affected by HIV. "To pretend that entire communities don't exist—in health, that doesn't make sense," Bertagnolli, the former NIH director, told me.

In several discussions that followed, officials with knowledge of those conversations said, Memoli assured NIH officials that health-disparity research could continue, as long as the inclusion of diverse populations in studies was "scientifically justifiable." But given the administration's disregard of scientific norms up until this point, "nobody was particularly satisfied by that explanation," one former official told me.

Still, on February 7, Memoli yielded a bit of ground: He green-lighted the NIH to start issuing a small subset of grants for clinical trials. That allowance fell far short of Lankford and other lawyers' recommendation to resume grant funding in full—but some officials wondered if the ice had begun to thaw.

That afternoon, Memoli acknowledged to other NIH officials that he understood what the agency's lawyers were telling him, an official with knowledge of the meeting told me. But then, he offered an alternative justification for holding back the agency's funds. What if, he said, the halt was continuing, not because the agency was adhering to the president's executive orders, but because it was pursuing a new agenda—a new way of thinking about how it wanted to fund research? Such shifts take time; surely, the agency couldn't continue its work until it had reoriented itself.

The lawyers were unmoved. At best, they said, that argument came off as a thinly veiled attempt to disregard court orders. Memoli contemplated this. He had no choice, he insisted: He was following the directions of three HHS officials—Dorothy Fink, then the acting secretary; Heather Flick Melanson, chief of staff; and Hannah Anderson, deputy chief of staff of policy—who had told him, in no uncertain terms, that the pause was to continue, save for the few award subtypes he'd already okayed. In other words, the Trump administration's political leadership at HHS wanted funding to stay frozen, and that overruled any legal concerns.

And, as officials learned later that day, HHS officials had been planning new ways to limit NIH funding. That afternoon, they foisted a new policy on the NIH that would abruptly cap the amount of funding that could be allocated to cover researchers' and universities' overhead. The first Trump administration had tried to cut those "indirect cost" rates in 2017; in response, Congress had made clear that altering them requires

legislative approval. And so within days, yet another temporary restraining order had blocked the cap.

Read: The NIH memo that undercut universities came directly from Trump officials

By this point, NIH lawyers were grim in their prognosis. If the agency moved forward with slashing indirect cost rates, they explained, individual staff members could be prosecuted for failing to comply with a congressional directive. On February 10, Sean R. Keveney, HHS's acting general counsel, sent a memo to Flick Melanson that included a directive in bold, italicized font: ***All payments that are due under existing grants and contracts should be un-paused immediately.***

Two days later, Lauer, the extramural-research director, issued a memo authorizing his colleagues to resume issuing awards—what should have been the agency's final all-clear to return to normalcy.

Even then, the staff remained divided on how to proceed. Some institutes immediately began sending out awards: Lauer's email spurred one institute, a current official told me, to process 100 grants in a single afternoon. Others, though, still held back. "They're scared out of their minds," the official told me. Some worry that, despite what Memoli has said, they'll be held accountable for somehow violating the president's wishes, and be terminated.

So far, at least 1,200 federal workers—many of them on probationary status—have been fired from the NIH; a new OMB memo released yesterday indicates that more layoffs are ahead. On February 11, HHS also attempted to unceremoniously reassign Tabak, the deputy director, to an essentially meaningless senior advisory position to the acting HHS secretary, with an office in another city, far from the laboratory he ran at the agency—a demotion that several NIH officials described to me as an insult. Tabak chose instead to retire that same day, abruptly ending his 25-year stint at the agency; Lauer, who had worked closely with Tabak for years, announced his own resignation that same week.

Their departures left many at the agency shocked and unmoored, several former and current officials told me: If Tabak and Lauer were out, was anyone's position safe? And because Lauer left immediately after clearing his colleagues to issue grants, who would ensure that the agency's core business would continue? "We're all still terrified for our jobs," one current official told me. Agency hallways, where colleagues once chatted and laughed, have sunk under an uncomfortable silence: "No one knows who they can trust."

The administration has also kept up its attempts to block NIH grants. Even after Lauer's memo went out, HHS continued to bar agency officials from posting to the Federal Register, the government journal that publishes, among other things, the public notices required by law for meetings in which experts review NIH grant applications and issue funds, one official told me. The NIH might have been *allowed* to award grants, but logistically, it was still unable to. Finally, on Monday, Memoli announced in a leadership meeting that the agency could resume submitting to the Federal Register. But there were limits: Although officials could post notice of some meetings to review grant proposals, meetings to finalize funding recommendations were still off the table—meaning the NIH would still be in a grant backlog. "We can't go crazy and put all our meetings on," Memoli told his colleagues. But if agency personnel responded to this new allowance reasonably, he said, they'd be granted more liberty.

Read: Grad school is in trouble

To Super, the administrative lawyer, curtailing posting to the Federal Register constituted yet another strategy intended to circumvent court orders. "These aren't legitimate workarounds," he said. "This is contempt of court." The NIH's developing plan to align the agency's strategies with the president's executive orders—which, officials told me, is still awaiting formal HHS approval—may end up being a legal battleground too: On Friday, a federal judge declared Trump's executive order attacking DEI programming a potential violation of the First Amendment.

The longer the pause on NIH funding has dragged on, the more the American research community has descended into disarray. Universities have considered pausing graduate-student admissions; leaders of laboratories have mulled firing staff. Diane Simeone, who directs UC San Diego's cancer center, told me that, should the pause continue for just a few more weeks, dozens of clinical trials for cancer patients—sometimes "a patient's best chance for cure, and long-term survival," she told me—could be at risk of shutting down.

Even if courts ultimately nullify every action that the Trump administration has taken, the NIH—at least in its current form—may remain in jeopardy. Robert F. Kennedy Jr., now the leader of HHS, has said that he wants to shift the agency's focus away from infectious disease and downsize the staff. Some Republicans have been pressing for years to slash the number of institutes and centers at the agency, which depends on Congress for its budget, or to disburse its funding to the states as block grants—a change, Bertagnolli told me, that could mean biomedical research in America "as we know it would end."

At a meeting with NIH leadership on February 13, Memoli explained to officials that "we are going to have to accept priorities are changing." He didn't say what those changing priorities might be, but previewed an era of "radical transparency," language that would headline an executive order from Trump just days later. In this moment, federal judges were "hampering us" from moving forward, into the agency's future, Memoli said. But the path before them remained the same: The NIH would do as the nation's leaders wished.

ABOUT THE AUTHOR



Katherine J. Wu

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

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EXHIBIT 43

National Institute on Deafness and Other Communication Disorders

Advancing the science of communication to improve lives

NDCD Advisory Council Meeting: January 2025

Event Date: January 23, 2025 - January 24, 2025

Time: Check event schedule

Location: Virtual Day 1 | Closed Session Day 2

Lecture Series: National Deafness and Other Communication Disorders Advisory Council (NDCD) Meetings

At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience.

January 23-24, 2025

Agenda (PDF | 188 KB)

*Note: PDF files can be viewed with the free Adobe Reader.

Last Updated Date: January 23, 2025

BACK TO TOP

National Institute of Allergy and Infectious Diseases

NIAID Council Agenda

At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience.

Content last reviewed on January 17, 2025



National Advisory Council on Minority Health and Health Disparities (NACMHD)

Public Health Service Act section 464z-3(j), 42 U.S.C. 285t(j), gives the Secretary of Health and Human Services the authority to establish an advisory council to provide advice regarding the Institute's research and research training activities with respect to minority health issues. The National Advisory Council on Minority Health and Health Disparities (NACMHD) advises the Secretary of Health and Human Services, the NIH Director, and the NIMHD Director on matters related to the NIMHD's mission.

Advisory Council's Approved Research Concepts

NACMHD Past Meetings

Upcoming Council Meeting

At the present time, all Federal advisory committee meetings have been canceled until further notice. Additional information will be forthcoming as it becomes available. We apologize for any inconvenience.

Future Council Meetings

Tuesday, May 6, 2025

Friday, September 5, 2025

Advisory Council's Approved Research Concepts

Interested in learning about approved research concepts before they are published as Notice of Funding Opportunities (NOFOs)? Review the Approved Research Concepts (/funding/approved-concepts/) page, which includes topical areas of research likely to become FOAs. Armed with this information, researchers can start thinking about assembling teams and pulling together information that could be the basis of a successful grant application.

Approved Research Concepts (../../funding/approved-concepts/index.html)

NACMHD Past Meetings

Date	Minutes/Agenda	Report(s)	Video
Sept. 2024	Minutes (PDF, 268 KB) (/docs/advisory-council/nacmhd_2024sept_minutes.pdf)/ Agenda (PDF, 124 KB) (/docs/advisory-council/nacmhd_2024sept_agendaOpenSession.pdf)	View director's report (PDF, 3 MB) (/docs/advisory-council/nacmhd_2024sept_dtrReportOpenSession.pdf)	View videoc (https://vide
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May 2023	Minutes (PDF, 314 KB) (/docs/advisory-council/nacmhd_2023may_minutes.pdf)/ Agenda (PDF, 53 KB) (/docs/advisory-council/nacmhd_2023may_agendaOpenSession.pdf)	View director's report (PDF, 3 MB) (/docs/advisory-council/nacmhd_2023may_dtrReportOpenSession.pdf)	View videoc (https://videc
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Feb. 2021	Minutes (PDF, 433 KB) (../../docs/advisory-council/nacmhd_2021feb_minutes.pdf)/ Agenda (PDF, 263 KB) (/docs/advisory-council/2021_NACMHD_agenda_feb.pdf)	View director's report (PDF, 2 MB) (../../docs/advisory-council/feb_2021_directors_report.pdf)	View videoc (https://videc

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Public Law 106–525—Nov. 22, 2000 (https://www.gpo.gov/fdsys/pkg/GPO-CDOC-106sdoc30/pdf/GPO-CDOC-106sdoc30-2-5-8.pdf)

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EXHIBIT 44

NIH Grant Review Meetings Cancelled FREE



January 23, 2025

The Trump administration abruptly cancelled NIH grant-review panel meetings, along with NIH travel and hiring, after all federal health officials were ordered to freeze public communications. The panels, also known as study sections, meet to review research grant proposals and award grants—which account for 80% of the agency's $47 billion budget and support research at more than 2,500 institutions—but researchers reported that meetings were cancelled without warning, preventing the distribution of research grants. The federal memo announcing the communications freeze said it would lift on February 1, but no end date was given for the cancellation of study section meetings.

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EXHIBIT 45

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASACHUSETTS

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

DECLARATION OF DENISE BARTON

I, Denise Barton, declare as follows:

1. I am a resident of the Commonwealth of Massachusetts. I am over the age of 18. I have been an attorney since 1994 and am licensed to practice in the Commonwealth of Massachusetts. If called as a witness, I could and would testify competently to the matters set forth below.
2. I am currently employed by the University of Massachusetts, in its Office of the General Counsel, as its Chief Deputy General Counsel.
3. As Chief Deputy General Counsel for the University of Massachusetts, I have personal knowledge of the matters set forth below or have knowledge of the matters based on my review of information and records provided to me by University of Massachusetts employees and believe that information to be true.
4. The University of Massachusetts includes its five campuses (the University of Massachusetts Amherst, the University of Massachusetts Boston, the University of Massachusetts Chan Medical School, the University of Massachusetts Dartmouth, and the University of Massachusetts Lowell), as well as the University of Massachusetts Office of the President.

See M.G.L. c. 75. The University of Massachusetts maintains business records in the ordinary course of University of Massachusetts business which include, *inter alia*, records concerning grant proposals submitted to and funding received from the National Institutes of Health ("NIH") by the University of Massachusetts.

5. I am providing this supplemental declaration in furtherance of my declaration (Dkt. 12-12, filed in this matter on April 4, 2025) to explain the mounting irreparable harmful impacts of NIH's abrupt and ill-supported cancellation of certain grants to the University of Massachusetts as well as the impacts of NIH's delay in evaluating applications for future grants, delay in funding projects that have passed peer review, and denial of grant applications without consideration of scientific merit.

6. The University of Massachusetts does not have available funds to replace the funds that NIH already committed to provide to it (as to the grants that were already awarded but which NIH abruptly terminated) nor does the University of Massachusetts have the funds necessary to proceed forward with paying for the costs (such as those for laboratory equipment and supplies, faculty salaries and fringe costs, and graduate student stipends and related funding) associated with the grants with fundable scores (see Dkt 12-12) for which NIH should already have finalized, or be close to finalizing, funding awards.

7. The University of Massachusetts cannot fund all of the costs associated with grants that NIH has terminated or delayed while this litigation proceeds and, as NIH continues to terminate and/or delay grant funding, the universe of the harm NIH is causing continues to expand, making it impossible to even calculate how much emergency funding would be required.

8. While the University of Massachusetts and its researchers are diligently endeavoring to identify alternative funding sources, given the nationwide impact of NIH's arbitrary and

abrupt action, all institutions and their researchers are seeking funds from the same finite potential replacement sources simultaneously and, as a result, it is a certainty that alternative external funding sources will be insufficient at best and wholly unavailable at worst.

9. Put plainly, the minimal emergency funding that the University of Massachusetts can provide to try to ameliorate a fraction of the harm caused by NIH's termination and delay of grant funding is at best, a glide path to different (but as yet unsecured) funding support for the same project, a switch to a different project or, in the worst case, a complete shutdown of the project. Cessation of work caused by NIH's conduct includes, but is not limited to, the termination of all of the work associated with the project, termination of the uniquely talented researchers who perform that work, and recission of students' admission to the programs of study that perform this work: in sum, NIH's conduct has caused and will continue to cause if left unchecked deep and irreparable harm to the students who have worked hard their entire academic careers to be admitted to these programs of study, the researchers who have completed those academic programs and are now devoted to the furtherance of not only the work but to the education of students in the work, and to the benefits the work will provide to the Commonwealth and, in many cases, all corners of the globe.

10. For example, because of NIH's arbitrary termination of some grants and its unexplained rolling blockade causing delay, at best, in the well-established approval process of other grants, as detailed in Dkt. 12-12, and because there are no other funds budgeted or available for expenses associated with these terminated and delayed grants, the University of Massachusetts Chan Medical School ("UMass Chan Medical School") has been forced to:

    a. Terminate and/or furlough 209 employees;

b. Cut the Fall 2025 incoming graduate student class size from 70 students to just 10 students;

c. Freeze all faculty and staff hiring; and

d. Stop other discretionary funding.

11. With the limited emergency funds that UMass Chan Medical School has been able to re-allocate, it has made a decision that it will use those funds to pay the stipends of current graduate students and post-baccalaureate scholars for the remainder of FY25 (through June 30, 2025).

12. UMass Chan Medical School does not have emergency funds to pay the costs associated with the grants NIH abruptly terminated nor does UMass Chan have emergency funds to pay the costs associated with the grant awards that NIH has improperly and arbitrarily delayed.

13. The University of Massachusetts Amherst ("UMass Amherst") does not have the funds to replace the financial deficit caused solely by NIH's arbitrary termination of some grants and rolling blockade of other grants, as detailed in Dkt. 12-12.

14. As circumstances currently stand, UMass Amherst will use its available emergency funds, currently projected to last through August 31, 2025, to support students, staff, and research faculty (whose salary is derived entirely from grants) so that they do not immediately have to be terminated. UMass Amherst also currently intends to use available emergency funding to support certain critical costs to preserve valuable research materials and/or pay for supplies to complete in-progress experiments through August 31, 2025.

15. To do this, UMass Amherst has been forced to reduce graduate admissions via rescission of funding offers to the human beings who had been accepted into various graduate programs. UMass Amherst has reduced graduate offers of admission to doctoral programs by 27%

for Fall 2025, and has rescinded funding offers from 100 accepted applicants. The reductions in offers of admission are largest in programs that rely significantly on NIH support, as set forth in the below table:

School/College & Program	Fall 2025 PhD Offers of Admission	Fall 2024 PhD Offers of Admission	Percentage Change
College of Engineering	112	160	-30%
College of Natural Sciences	283	405	-30%
Manning College of Information and Computer Sciences	84	147	-43%
School of Public Health & Health Sciences	31	62	-50%
Campus wide PhD Offers of Admission	805	1099	-27%

16. In sum, UMass Amherst will use the emergency funding it has available to give those impacted by NIH's abrupt actions time to either finish up a degree, find a new project, or secure a new (or delayed) source of funding but, to do so, it has had to significantly reduce the number of incoming students.
17. NIH continues to worsen the depth and breadth of irreparable harm to the University of Massachusetts, its researchers, its faculty, its students, the Commonwealth, and the forward progress of scientific knowledge.
18. For example, in addition to the exemplars set forth in Dkt. 12-12, NIH cancelled NIH AG077672-04S1 on April 7, 2025, a diversity supplemental award to UMass Amherst entitled "Deciphering the Molecular Features Underlying LRP1-Mediated Tau Spread (Parent Grant)" stating, "The Diversity Supplement program is no longer supported by NIH/HHS priorities."

19. Also by way of example, since submission of the original declaration (Dkt. 12-12), NIH has sent "program cancellation notifications" to UMass Chan Medical School on the following:

    a. 1F31GM157877-01: "Engineering bacterial group I introns for efficient production of safe and durable nucleoside-modified circular mRNA therapeutics."

    b. 2T32GM135751-06: "IMSD at the University of Massachusetts Chan Medical School."

    c. 5R25GM121220-08: "Pathway to graduate study post-baccalaureate training program."

20. Since submission of the original declaration (Dkt. 12-12) UMass Chan Medical School has received information that NIH will be cancelling the following grants:

    a. Subaward from Harvard School of Public Health: IMPAcTB 75N93019C00071: On April 5, 2025, UMass Chan Medical School was notified by Harvard School of Public Health that the award was under review and likely to be cancelled by NIH.

    b. On April 10, 2025, UMass Chan Medical School received a notification from the University of Alabama that their program, on which UMass Chan Medical School is a subawardee, is being cancelled by NIH.

    c. 5R01MD019235-02 "TANGO Program" cancellation notice received on April 3, 2025 at 4:04 p.m. by the University of Alabama at Birmingham from NIH which stated: "I am writing to inform you of an important update regarding funding for the TANGO project. As of April 1, 2025, the National Institutes of Health (NIH) will no longer be providing funding

for this initiative. Consequently, enrollment activities at the University of Massachusetts (UMass) and Brigham and Women's Hospital (BWH) will need to cease effective immediately. Given this update, we will be cancelling the TANGO Investigators meeting tomorrow."

21. In addition, a UMass Chan Medical School senior faculty member and administrator was scheduled to chair an ad hoc study section for the National Heart Lung and Blood Institute ("NHLBI") of NIH on April 23, 2025 for the National Gene Vector Biorepository ("NGVB"), which is an NHLBI funded core supporting the NHLBI's gene therapy portfolio. Like any other NIH grant, this matter is subject to the process of peer review, study section, and advisory council as described in the original declaration (Dkt. 12-12). On April 9, 2025, NIH held the "pre-review orientation" and there was no mention of any delay. Then, on April 10, 2025, NIH sent an email stating, "I have received information that we may need to pause the NGVB review. Please pause your reviewing activities until I receive further guidance." As of April 14, 2025, NIH has sent no follow-up communication regarding this study section.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on April 14, 2025, at Westborough, Massachusetts.

/s/ *Denise Barton*
Denise Barton
Chief Deputy General Counsel
University of Massachusetts, Office of the General Counsel
50 Washington Street
Westborough, MA 01581

EXHIBIT 46

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR, et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF SALLY MORTON

I, Sally Morton, declare as follows:

1. I am a resident of the State of Arizona. I am over the age of 18 and have personal knowledge of all the facts stated herein, except to those matters stated upon information and belief; as to those matters, I believe them to be true. If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by Arizona State University (ASU) as Executive Vice President of the ASU Knowledge Enterprise and as a Professor in the Colleges of Mathematical and Statistical Sciences and the College of Health Solutions. In my capacity as Executive Vice President, I lead the university's research and economic development portfolio to advance research priorities, oversee ASU's research institutes and initiatives, and drive corporate engagement, strategic partnerships, intellectual property, and technology transfer.

3. ASU is a comprehensive public research university committed to advancing research and discovery of public value. ASU is one of the fastest growing research institutions in the U.S., with research expenditures of $904 Million in the fiscal year ending June 30, 2023.

4. ASU enrolls more than 180,000 students, who can choose from more than 400 undergraduate academic programs and majors and more than 450 graduate degree programs and certificates.

5. ASU's research work spans all 16 of its colleges and schools and involves a vast array of topics and research goals, including human health, technology, and national security.

6. The economic impact of ASU's work has been estimated as $5.75 billion in Arizona gross product in the fiscal year 2023, including the creation of jobs, patenting of inventions, and attraction of private investment in university inventions.

7. Funding from federal agencies constitutes a significant portion of ASU's annual research expenditures. In the fiscal year ending June 30, 2024, ASU expended approximately $508 million received from federal agencies to conduct work under approved agreements (grants, contracts, and cooperative agreements).

8. ASU receives grant funding from at least 23 different federal agencies, including the United States Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Homeland Security, Labor, and State; the United States Agency for International Development; the United States Environmental Protection Agency; the National Aeronautics and Space Administration; and the National Science Foundation.

9. The National Institutes of Health approved 99 ASU projects (including subawards) scheduled to begin in the fiscal year ending June 30, 2024, with a total anticipated amount of approximately $104 million. ASU's NIH-funded research relates to topics of central importance to human health, including the causes and treatments of chronic disease, cancer and opioid addiction as well as the use of technology such as artificial intelligence to promote health outcomes.

10. As of the date of this declaration, five of ASU's NIH-funded projects have been paused or terminated, and ASU continues to receive new grant-related notices on an ongoing basis.

11. ASU also has more than 450 proposals with an estimated amount of $711 million that have been submitted to NIH but for which it has not received a response.

12. The nature of scientific research, including health research, is that it is often cumulative, with research teams seeking subsequent grants to build on prior discoveries.

13. Ongoing research is also essential to the education of students, as the ability to participate in research projects led by experienced faculty is a core part of training them to be successful scientists in the future.

14. Any actions by NIH that delay or suspend funding for ongoing and proposed research may result in the loss of research materials or the need to re-do work that is underway, and thereby delay scientific discoveries and impair the competitiveness of the university's research program. Interruptions in the funding needed to continue research may also result in the loss of employees with specialized expertise, including on projects that may later be resumed, and may affect the progress of students in their degree programs.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 4, 2025, at Washington, District of Columbia.



Sally Morton

EXHIBIT 47

In the UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

FIRST SUPPLEMENTAL DECLARATION OF JASON A. WILDER

I, Jason A. Wilder, hereby declare:

1. I submit this First Supplemental Declaration to supplement the Declaration of Jason A. Wilder. *See* ECF No. 12-13.
2. Northern Arizona University (NAU) received notification from the National Institute of General Medical Sciences on April 2, 2025 that its "Bridging Arizona Native American Students to Bachelor Degrees" was terminated due to "changes in NIH/HHS priorities". This five-year award to NAU was terminated after its 4th year of activity, and thus NAU will forgo recruitment of the final cohort of students who would have benefited from this program. Activites associated with this program will cease on July 31, 2025.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 13th day of April, 2025, in Flagstaff, Arizona.



Jason A. Wilder
Vice President for Research
Northern Arizona University

EXHIBIT 48

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF MARCUS CRAWFORD, Ph.D.

I, Marcus Crawford, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated here. If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by California State University, Fresno as an Associate Professor in the Department of Social Work Education and have held that position since August 2018.

3. My current responsibilities include but are not limited to acting as the Principal Investigator for the Research Centers in Minority Institutions ("RCMI") grant (RFA-MD-24-012, U54), a grant submitted to the National Institutes of Health ("NIH") and currently under review.

4. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

5. The RCMI grant is a five-year award that would create a multi-core research center at California State University, Fresno with the purpose of expanding the university's capacity to conduct world-class research in the health sciences in the Central Valley of California. The grant is specifically designed for universities without significant NIH funding that serve historically underrepresented student populations in communities with significant populations with unmet health needs, criteria that matches California State University, Fresno

and its geographic region. The cores within the center are focused on increasing research capacity, enhancing investigator development, and fostering community engagement.

6. We submitted the RCMI grant on November 19, 2024 with a decision date by the end of May 2025 and a start date of July 1, 2025. NIH grants have two levels of review: the scientific review meeting followed by the council review. The scientific review meeting was originally scheduled in February 2025 (with no specific date). This date has changed several times after January, first to mid-March, then to April, then to June; presently, no date is listed. The council review date was scheduled in May but was recently changed to August 2025. The start date remains July 1, 2025, but this won't be possible with a council date in August 2025. For the most part, I discovered these changes myself when checking on the status of the grant. I received one notification of a change at the end of March 2025, which is when I first noticed that the scientific review date had been moved to June 2025. When I checked on a subsequent date, I found the review date had been removed altogether and a code was listed in its place. I have contacted the grant manager twice to seek clarity about the review date but have not received a response to my inquiry.

7. The delay in scheduling negatively impacts our ability to plan for the implementation of the grant. A grant of this size requires many people working collaboratively. We have 12 people listed on the grant with various roles across 3 colleges and 9 departments. Faculty working on this grant will receive time released from teaching ranging from 25% to 50%

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but cannot plan for this while the grant remains under review with changing implementation dates.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on April 12, 2025, in Clovis, California.

Marcus Crawford (Apr 12, 2025 08:32 PDT)

Marcus Crawford, Ph.D.

EXHIBIT 49

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF JENI KITCHELL

I, Jeni Kitchell, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated in this declaration, except to those matters stated upon information and belief; as to those matters, I believe them to be true. If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by the California State University as Assistant Vice Chancellor, Finance & Budget Administration and Controller.

3. As the Assistant Vice Chancellor, Finance & Budget Administration/Controller, I am responsible for oversight of financial operations at the CSU and financial reporting from all sources, including federal funding.

4. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

5. The total NIH grant monies at issue for the California State University and its auxiliary organizations total approximately $20.2 million. Without a preliminary injunction that restores funding of each NIH grant to each of the affected CSU university campuses, neither the California State University nor any of its auxiliary organizations will have the financial resources to keep the programs running.

6. The CSU's operating budget does not have any available funds to cover these programs, should federal funding be terminated. The CSU's operating budget has two main funding sources: the state General Fund (as appropriated by the Legislature annually), covering about 60% of the educational budget, and student tuition and fees, which cover the rest. The CSU

has been challenged with budget gaps of $138 million in 2023-24 and $218 million in 2024-25, which it addressed in part through reducing course sections (equivalent to 35,000 student seats) and suspending or discontinuing 136 degree programs; implementing personnel reductions and program restructuring; pausing and deferring capital and maintenance projects; and cutting operational and discretionary spending. The rest was covered by spending down operational reserves. The CSU also approved a tuition increase to take effect starting in 2024-25.

7. Despite these actions (and the anticipated increased tuition), the CSU is facing an even larger budget gap in 2025-26. The state General Fund appropriation is proposed to decrease by 7.95% ($375 million), an amount equivalent to the funding needed to educate and support more than 34,000 full-time equivalent students. The tuition increase will just cover increases to baseline commitments for that fiscal year (i.e., increases in financial aid, healthcare premiums, liability and property insurance, utilities and maintenance of new facilities) without closing any of the remaining $375 million budget gap or allowing for funding of any of CSU's currently-unfunded essential priorities (e.g., compensation increases, student success initiatives and basic needs, infrastructure investments; totaling approximately $593 million). There is no additional public funding or student tuition money available to cover another $20 million in lost NIH grant program funding which, up to this point, has been reliably predictable as a funding source over multiple years.

8. The California Legislative Analyst's Office issues a California Fiscal Outlook at the start of the annual budget cycle. In November 2024, the LAO's outlook warned of continuing significant budget challenges through the 2028-29 fiscal year that will continue to result in reduced General Fund allocations to CSU. (See https://lao.ca.gov/Publications/Report/4957) For example, the LAO stated that "[g]iven the

state's projected budget deficit in 2026-27, the state likely will not have budget capacity to support substantial increases in General Fund spending for any programs, including for CSU." The LAO acknowledged that baseline commitments for CSU are growing annually, but stated that CSU "would need to make room for any such costs by adjusting other parts of their budgets." There is insufficient funding to cover CSU's operating costs for this fiscal year – let alone to bridge loss of funding for NIH programs. Because the purpose of CSU as established by California Education Code section 66010.2 is to provide access to education and the opportunity for educational success for all qualified Californians, CSU does not have the discretionary option *not* to spend its funds as required to fulfill its educational mission.

9. CSU's budget includes many items that are based on long-term commitments and planning efforts, including phased campus development under multi-year master plans, deferred maintenance schedules, and bond financing repayments. These funds are already committed, sometimes for many years in the future, and thus are not available to replace lost funds from the NIH programs. Moreover, the annual budget process is a lengthy one, with various components reviewed and evaluated months, and sometimes years, before actual funding is allocated. This also applies to grant funding, which is sought and secured well in advance of its use, necessitating personnel and equipment purchases based on those commitments. Abrupt and significant changes in circumstances, such as the loss of NIH funding, cannot be seamlessly absorbed into the ongoing budget process.

10. CSU cannot rely on its operating reserves to fund the NIH programs. As of June 2024, CSU had $2.4 billion in reserves to support the core operations of the 23 university campuses and the Chancellor's Office, of which only $777 million was not obligated for a specific purpose and therefore was available to address economic uncertainty. This amounts to

33 days of operation for the entire system, an amount that the LAO noted is far below the reserve policy, which stipulates that reserves cover from three to six months of operations. CSU university campuses used their reserves to bridge budget gaps in 2023-24 and may need to do the same in 2024-25 and the coming years.

11. CSU auxiliaries are nonprofit organizations that are authorized under the California Education Code to provide certain specified essential supplemental services and support to the CSU university campuses. CSU auxiliaries operate within policies established by the CSU and wholly within written operating agreements with the affiliated CSU university campus to perform limited and specific functions that contribute to the educational mission of the university, including management of "Externally Funded Projects Including Research, Workshops, Conferences, and Institutes".

12. Like the universities they serve, CSU auxiliaries are also economically strained and do not possess or generate sufficient revenue to replace lost grant funding. CSU auxiliaries do not have the financial resources available to replace the loss of NIH funding. The auxiliary organizations were hit hard during the COVID-19 pandemic, as a significant portion of their revenue comes from in-person activities on campus, and they have yet to recover from that multi-year loss of revenue.

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13. CSU is facing dire fiscal challenges. Without the NIH grant funding, CSU will have to shutter these programs and may need to take additional measures that would adversely affect the university community – faculty, staff and students – both directly and indirectly.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on April 12, 2025, at Long Beach, California.

Jeni Kitchell (Apr 12, 2025 08:08 PDT)

Jeni Kitchell

EXHIBIT 50

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814

DECLARATION OF JOHN E. POOL

I, John E. Pool, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a Professor of Genetics within the College of Agriculture and Life Sciences at the University of Wisconsin-Madison ("UW-Madison"). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UW-Madison staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for a Preliminary Injunction.

3. I have been a Professor of Genetics (or, previously, Assistant or Associate Professor) at UW-Madison since 2011. I also serve as the Director of the J.F. Crow Institute for the Study of Evolution and am a Core Faculty member of the UW-Madison Center for Genomic Science Innovation, an Affiliate Faculty in the UW-Madison Department of Integrative Biology, and a Faculty Mentor in the Genome Sciences Training Program. I received my PhD in Genetics and Evolution from Cornell University and my Bachelor of Science in Biology from Western

Michigan University. My research focus is in the area of population genomics and the genetic basis of adaptive evolution.

4. I submit this declaration to provide information regarding the unexpected procedural delays and irregularities I am currently experiencing as Principal Investigator on a renewal of an R35 grant from NIH's National Institute of General Medical Sciences (NIGMS), and the profound impacts of those delays on my laboratory. I have experience with NIH grants, including an NIGMS R35 grant that I held from April 2020 through March 2025 (the renewal of which is the subject of this declaration), as well as two NIGMS R01 grants and an earlier F32 postdoctoral fellowship.

5. The research program funded by the R35 grant, "The Architectures and Underpinnings of Adaptive Evolution and Reproductive Isolation," uses a cost-effective laboratory model organism (the Drosophila fly) to investigate fundamental principles of evolutionary biology at the genetic level, including how natural populations adapt to new environments, and what the earliest steps toward becoming two different species entail. This research informs the underpinnings of human trait variation, with relevance to many diseases. The research also clarifies how biomedically important insects are likely to evolve. Additionally, the focus on genetic incompatibilities may inform our understanding of the causes of miscarriage and human infertility, and the health consequences of Neanderthal genetic variants found in most individuals of non-African descent.

6. The grant renewal was for a five-year period that was to commence on April 1, 2025 and has $2.8M in budgeted funding. It is the only grant funding supporting my lab.

7. The study section for my R35 renewal application met in October 2024 and NIGMS indicated that the expected advisory council date would be January 2025. The advisory council

was then scheduled for February 6, 2025, but was canceled without explanation. The advisory council has now been rescheduled to May 22, 2025. But that date—if it holds, which is uncertain, given all the irregularities thus far—is highly problematic, as the R35 grant that is being renewed already ended on March 31, 2025. Because this was my lab's only grant, this delay has caused the lab's funding to lapse.

8. I have also received concerning communications from the NIGMS program officer indicating further delays may be expected, even after the advisory council meeting scheduled for late May. In my experience, the grant would typically issue promptly after advisory council, but my program officer indicated that a funding decision may occur as late as September 2025 and that funding might not begin until after that date.

9. This renewal process has been highly unusual and this delay was unforeseeable. Renewal rates for R35 grants are typically very high, close to 80%, and my lab has been very productive during the previous funding period for this grant. Prior to these delays, the program officer had given me only positive indicators regarding the likelihood of renewal. The renewal proposal had a score of 38 which, per NIGMS' guidance, could reasonably be expected, for an established investigator like me, to be funded at generally as high a frequency as any better score. In a rather cruel twist, R35 grants are promoted to investigators as a stable funding source, and R35 recipients are required to give up other NIGMS grants in order to receive an R35 award. Paradoxically then, accepting this supposedly stable mechanism puts labs like mine in an especially vulnerable position in the face of this unpredictable volatility at NIGMS.

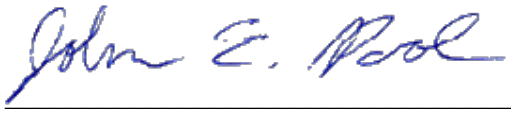
10. The delays (thus far) have already harmed my lab's ability to function. As a result of the lapse in funding caused by the delayed advisory council, I lost a senior researcher, who had been funded 50% by the R35 grant, leaving some research unfinished due to the hasty

transition. My lab now has just one staff member, a key researcher who is essential to this program. My ability to continue to pay this researcher is entirely dependent on bridge support from the University (which is unknown at present in light of the overarching budgetary uncertainty and unpredictability stemming from actual and expected changes in federal research funding practices) and the unclear timing and outcome of the R35 renewal application.

11. One PhD student is also acutely impacted by this funding lapse; the lab has no funding to pay him, making his progression towards finishing his degree uncertain. I also declined to recruit a graduate student in light of the lab's completely unpredictable financial outlook.

12. Because of the all of the uncertainty, I am simply unable to make any well-informed budgeting decisions on a short- or long-term basis, jeopardizing my laboratory's work and the contributions the lab makes to the endeavor of science and to human health.

Executed this 13h day of April, 2025, in Madison, Wisconsin.



John E. Pool, PhD

EXHIBIT 51

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 25-cv-10814-BEM

DECLARATION OF SUSANNAH PORTERFIELD, Ed.D.

I, SUSANNAH PORTERFIELD, Ed.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President of Research at Kean University. I have personal knowledge of the facts set forth in this declaration, and/or am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the Kean University Office of Research and Sponsored Programs' staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for a Preliminary Injunction.

Professional Background

3. I became the Vice President of Research at Kean University in April 2023. Prior to that, I was employed by Johns Hopkins University for 20 years. I have a doctorate in organizational leadership from Stockton University in New Jersey. I also have a master's degree in human

resource management from Towson University in Maryland and a bachelor's degree in business management and psychology from Grove City College in Pennsylvania.

Institution Overview

4. Kean University is a vibrant public urban research institution of the State of New Jersey and was recently designated as an R2 research university under the Carnegie Classification of Institutions of Higher Education, marking a significant milestone in Kean's rapid transformation into a premier research institution.

5. Kean is home to a diverse student population and is designated by the U.S. Department of Education as a Hispanic-Serving Institution. The majority of the undergraduate students majoring in STEM and health-related sciences identify as underrepresented, first-generation college students or English as second language learners. Over 65% of undergraduates who self-disclose ethnicity are from underrepresented groups. In addition, 52% of Kean's students are first-generation college students, 80% of first-year students are awarded need-based financial aid, and 48% of independent undergraduates fall below the federal poverty level.

6. As the fourth largest state institution in New Jersey, Kean offers 50 undergraduate degrees, 60 graduate degrees, six doctoral programs and 23 online programs. The student body of Kean's main campus in Union, New Jersey is approximately 11,800, is drawn primarily from the surrounding urban area and reflects the area's ethnic diversity. In the past decade, the numbers of first-generation, transfer, and minority students have increased, and the administration is responsive to changing student needs.

7. The Dorothy and George Hennings College of Science, Mathematics, and Technology (HCSMT), which serves about 2,400 students (55% from groups underrepresented in the sciences), is strongly, though not exclusively, addressed to biomedicine and relevant fields.

8. Kean has implemented many programs designed to increase the number of underrepresented groups who persist and graduate. Kean's Center for Advising, Persistence, and Success in the Division of Student Success and Retention provides culturally responsive academic advising, evidenced-based programming, educational planning and positive academic transitions for matriculated and undeclared freshman, sophomore and transfer students. The Office for Student Retention & Educational Innovation provides programming and support towards persistence, retention, and timely graduation. Moreover, and more specifically, the office aims to support and develop student programming that enriches experiences, builds cohesion, and a sense of belonging to the University, and fosters warm relationships with peers, faculty members, and staff. Academic support and tutoring services are provided on campus at the Nancy Thompson Learning Commons. With Kean University's diverse student body, support from NIH programs helps fulfill the mission and vision of the University by encouraging and supporting diversity and inclusion in the biomedical sciences.

NIH Delay and/or Cancellation of Study Sections

9. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

Reliance on NIH Funding

10. In fiscal year 2024 (July 1, 2023-June 30, 2024), Kean had six active projects supported by the National Institutes of Health ("NIH"), totaling $133,000 in expenditures.

11. Kean receives NIH grants across a variety of institutes encompassed within the NIH, including Aging, General Medical Sciences, and Child Health and Human Development.

12. Through those NIH grants, Kean funds seven researchers and many students.

13. The work done by Kean on NIH funded projects provides education and training in Biology, Biomedicine, Chemistry, Computer Science, Environmental Science, and Mathematical Sciences.

14. Kean provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New Jersey economy.

Typical Timeline and Processes for NIH Grant Awards

15. The Office of Research and Sponsored Programs at Kean works with researchers to submit grant applications and tracks grant applications and awards.

16. As the Vice President of Research, I have an understanding of the NIH grant process based on my 20+ years of experience.

17. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

18. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of

grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

19. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

20. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

21. The budget process at Kean relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within nine months of submission.

22. Once a grant receives a score, Kean is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

23. Since late January 2025, Kean has seen delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

24. Kean has not received formal notice of changes for many of these grants. For others, Kean has gotten only a notification that proposals are "paused" or "under review."

25. As of April 11, 2025, Kean has six proposals totaling approximately $11 million awaiting NIH study section review, advisory council and/or Notice of Award.

Termination of Grants

26. Since January 20, 2025, Kean has had one NIH grant terminated.

27. The termination notice received as of April 2, 2025 is attached hereto as Exhibit A.

28. This termination will result in the loss of $1,223,824 in research money to Kean.

29. The termination notice for this grant has provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." *See* Exhibit A.

30. The following ostensibly boilerplate language was used to justify the termination: "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." *See* Exhibit A.

31. In my time working at Kean and at Johns Hopkins, I have not seen this language previously used to cancel grants.

32. The termination notice also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. *See* Exhibit A. However, prior to receipt of the termination, Kean had not been given notice of any opportunity to submit any "corrected" grant

materials to align with agency priorities. Nor was Kean provided with any updated "agency priorities" with which its research must align.

Kean University U-RISE Trainee Pathway
(Award Number: 1T34GM149448-01A1)

33. The Kean University U-RISE Trainee Pathway (KUTP) was proposed to expand the School of Integrative Science and Technology's (IST) undergraduate research pathway to increase the flow of graduates into graduate programs and research careers in biomedicine. It was designed serve a total of eight (8) fellows (a total of twenty (20) for the five-year program) recruited from all science departments, the majority of whose students are underrepresented minorities or first generation. Fellows were to receive financial support, intensive triad mentoring, and rigorous academic and research-skills training.

34. KUTP received its initial year of funding beginning April 1, 2024. The program was proposed to last five years and was expected to be renewed beyond the initial funding period. Years 1 and 2 would work to enhance the IST's existing Research First undergraduate initiative by adding advanced training in the responsible conduct of research and new cohort activities to increase sense of belonging, self-efficacy, and STEM identity. Years 3 and 4 were to include more advanced, independent research projects and professional development activities. Finally, KUTP fellows and other science students would be supported in making the transition to graduate school and the biomedical research workforce and would be called upon to mentor students still in the program. Drawing on Kean's extensive expertise in the training of underrepresented minorities, KUTP incorporated data-driven mechanisms to create sustainable programmatic experiences and establish a model that could be applied more broadly at Kean and other institutions.

35. KUTP recruitment would extend and enhance IST's extraordinary Group Summer Scholars Research Program for high-school students. In this six-week, hands-on research

experience for 30 to 50 high school students interested in pursuing an education in a STEM field, participants would work alongside faculty and graduate student mentors on cutting-edge research projects in Kean's state-of-the art labs and facilities in Union, NJ. Enhancing recruitment would enlarge both the KUTP trainee pool and the flow of graduates into STEM majors and research careers.

36. KUTP was awarded $152,978 for its first year. *See* Exhibit B. Kean University anticipated receiving funding for KUTP in the amount of $305,956 annually for each of the five years remaining on the grant (2025, 2026, 2027, and 2028) to fund the program and support KUTP Fellows. *See* Exhibit B.

37. As a result of the termination letter, Kean University expects a prospective loss of $1,223,824 in funding for KUTP across the remaining 2025, 2026, 2027, and 2028 grant years.

38. As a result of the loss of funding, the U-RISE program will be terminated and Kean undergraduates will lose the chance to train in research excellence, unite in a diverse cohort to build identity, and prepare for the next phase of their biomedical research career pathway.

Comparisons Across Administrations

39. In prior years, under both Democratic and Republican administrations, our institution never experienced these unexplained delays or procedural breakdowns.

40. Renewals were routine and predictable.

41. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Concerns About FY25 Funds Being Obligated

42. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in June.

43. Major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

44. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

45. Without the U-RISE federal grant funding, the program will be terminated, and the goals of the program will not be achieved. Without NIH support, fewer students, especially those from underrepresented or lower-income backgrounds, will have access to meaningful research experiences. Early research exposure, like U-RISE, is a key factor in students pursuing graduate programs and scientific careers.

46. Kean is unable to reallocate enough funding to offset federal grant award delays and losses in federal grant funding. Federal grant award delays and terminations have disrupted ongoing research and will set Kean back in research going forward.

Conclusion

47. The breakdown in NIH processes is affecting institutional operations, budgeting and research progress. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in some instances, irreparable.

Susannah Porterfield
SUSANNAH PORTERFIELD, Ed.D.

Date: April 12, 2025

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

4/2/2025

Susanna Porterfield
Kean University
sporterf@kean.edu

Dear Susannah Porterfield:

Funding for Project Number 1T34GM149448-01A1 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 April 1, 2024 and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Matthew J. Memoli, M.D., M.S., Acting Director, NIH no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT B

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# T34GM149448
Federal Award Date
03/25/2024

Recipient Information

1. Recipient Name
KEAN UNIVERSITY
1000 MORRIS AVE
UNION, NJ 07083

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1222960726A1

4. Employer Identification Number (EIN)
222960726

5. Data Universal Numbering System (DUNS)
155943111

6. Recipient's Unique Entity Identifier
SQ62WM5KNSV8

7. Project Director or Principal Investigator
Derrick Swinton (Contact)

dswinton@kean.edu
(908) 737-7223

8. Authorized Official
Ms. Sherrie Calish

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
MARIE DEBORAHGAYNELLE Harton

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
marie.harton@nih.gov
(301) 594-1554

Federal Award Information

11. Award Number
1T34GM149448-01A1

12. Unique Federal Award Identification Number (FAIN)
T34GM149448

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
Kean University U-RISE Trainee Pathway (KUTP)

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2024 **– End Date** 03/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$152,978
20 a. Direct Cost Amount	$144,328
20 b. Indirect Cost Amount	$8,650
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$152,978
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$152,978
26. Project Period Start Date 04/01/2024 **– End Date** 03/31/2029	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$152,978

28. Authorized Treatment of Program Income
Other Research (Add/Deduct Option)

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.

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Notice of Award

MARC NATIONAL RESEARCH SERVICE AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 1T34GM149448-01A1

Principal Investigator(s):
Salvatore John Coniglio, PHD
Matthew Gene Niepielko, PHD
Derrick Swinton (contact)

Award e-mailed to: sporterf@kean.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $152,978 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to KEAN UNIVERSITY 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 T34GM149448. 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)

Stipends	$57,360

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Tuition & Fees	$36,200
Trainee Travel	$11,000
Training related Expenses	$39,768
Federal Direct Costs	$144,328
Federal F&A Costs	$8,650
Approved Budget	$152,978
Total Amount of Federal Funds Authorized (Federal Share)	$152,978
TOTAL FEDERAL AWARD AMOUNT	$152,978
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$152,978

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**
1	$152,978	4			$152,978	4		
2	$305,956	8			$305,956	8		
3	$305,956	8			$305,956	8		
4	$305,956	8			$305,956	8		
5	$305,956	8			$305,956	8		

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1222960726A1
Document Number:	TGM149448A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027	2028
GM	8472205	$152,978	$305,956	$305,956	$305,956	$305,956

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: T412MH / **OC**: 41010 / **Released**: Rosenzweig, Justin 03/18/2024
Award Processed: 03/25/2024 05:12:10 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1T34GM149448-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1T34GM149448-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain

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references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) T34GM149448. 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

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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:
Other Research (Add/Deduct Option)

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 1T34GM149448-01A1

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Informational Term – Ongoing review of findings in prior single audit report(s): NIH is conducting a retrospective review of KEAN UNIVERSITY's most recent single audit report based on our identification of findings reported in prior single audits. Based on the outcome of this retrospective review, NIH may unilaterally take administrative action to safeguard NIH funds in accordance with the NIH Grants Policy Statement, Section 8.5.1 "Specific or Special Award Conditions- Modification of the Terms of Award."

1. This grant must be administered in accordance with the guidelines and restrictions described in the Initiative for **Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program announcement** (PAR-21-146) available at: https://grants.nih.gov/grants/guide/pa-files/PAR-21-146.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 Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program as well as answers to Frequently Asked Questions, please visit: https://www.nigms.nih.gov/training/RISE

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-23-076 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-076.html)

4. SUMMER RESEARCH EXPERIENCE: This award includes $7,000 to support the Summer Research Experience (SRE) for 50% of the total trainee slots awarded. These funds are based on $3,000 per trainee slot for per diem expenses for ten weeks and $500 for travel plus 8% F&A costs. They are restricted solely for this purpose and may not be rebudgeted into other categories. Additionally, funds have been included in future years for this purpose. **Travel to foreign sites (a country other than the United States and its territories) is not allowed for any trainee while appointed to the grant.** Please review the SRE guidelines posted at https://www.nigms.nih.gov/training/T34/Pages/sre.aspx

5. 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.

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6. This award includes funds to support four (4) trainees (48 Trainee Months). The maximum number of trainees that may be appointed without the prior written approval of NIGMS staff is 5 (60 Trainee Months) if funds are available through rebudgeting.

7. 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.

8. In accordance with NIH Guide Notice NOT-OD-10-072, appointment documentation 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

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. Failure to submit documentation may result in an expenditure disallowance or a delay in continued funding.

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.

9. 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.

10. **The next non-competing progress report for this grant is due on August 15, 2024**.

11. 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

12. 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.**

13. In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

NIGMS' OFFICIAL WEBSITE

The NIGMS WWW home page is at http://www.nigms.nih.gov

Data Management and Sharing Policy: Not Applicable

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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: 1T34GM149448-01A1

INSTITUTION: KEAN UNIVERSITY

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EXHIBIT 52

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al., *Plaintiffs,* v. ROBERT F. KENNEDY, JR., et al., *Defendants.*	No. 25-cv-10814-BEM

DECLARATION OF JOHN A. PELESKO, PH.D.

I, John A. Pelesko, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Provost and Senior Vice President for Academic Affairs of the New Jersey Institute of Technology ("NJIT"). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the NJIT staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for a Preliminary Injunction.

Professional Background

3. I am the Provost and Senior Vice President for Academic Affairs at NJIT. I have served in this capacity since 2023. Previously, I served as the Dean of the College of Arts and Sciences at the University of Delaware. I have also held faculty positions at Georgia Institute of Technology and California Institute of Technology.

Institution Overview

4. NJIT was founded in 1881 as the Newark Technical School, becoming the Newark College of Engineering in 1930. Today, NJIT has six schools and colleges: Newark College of Engineering (1930), the Hillier College of Architecture and Design (1973), the College of Science and Liberal Arts (1982), the Martin Tuchman School of Management (1988), the Albert Dorman Honors College (1993), and the Ying Wu College of Computing (2001).

5. NJIT is a polytechnic university and its designation as a Very High (R1) Research Activity doctoral institution was reaffirmed by the Carnegie Classification of Institutions of Higher Education, placing NJIT among 146 of the most elite and productive research institutions in the nation and one of three in New Jersey. As New Jersey's public, polytechnic research university, NJIT enrolls approximately 13,000 students across its six schools and colleges.

6. As an R1 research-active university, NJIT's vision is to provide undergraduate students with a STEM focused education through research training and mentorship in order to produce the future generation of scientists and engineers. NJIT is also one of the largest producers of engineers and computer scientists in the tri-state area.

7. NJIT has over 140 labs, centers, and institutes that strive to lead in five areas of multidisciplinary research: bioscience and bioengineering, data science and management, environment and sustainability, material science and engineering, and robotics and machine intelligence. NJIT is continuously growing its research enterprise with approximately $167 million of annual research expenditures in FY2023. NJIT aims for national and international prominence in research through new discoveries in areas ranging from medical sensors and devices to robotics, nanotechnology, and cybersecurity, to next-generation materials, among other topics of vital importance in basic, applied, and translational research.

8. NJIT's statutory mission is as a public research university, deemed to be public and essential governmental functions necessary for the welfare of the State and the people of New Jersey.

9. NJIT employs 560 researchers and 230 technicians.

National Institutes of Health Delay and/or Cancellation of Study Sections

10. The National Institutes of Health's ("NIH") abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

11. The NIH meeting blockade severely impacts NJIT by delaying the scholarship of faculty, which impedes progress towards tenure, risking the continuity of research in certain programs, and restricts NJIT's ability to train the next generation of scientists.

Reliance on NIH Funding

12. In fiscal year 2024, NJIT received funding through the NIH to support 24 projects, totaling approximately $4.3 million.

13. Through those NIH grants, NJIT supported a total of $1,823 million in personnel and fringe expenditures, including student support, in whole or in part, for fiscal year 2024.

14. The work done by NJIT on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Biology, Mathematics, Chemistry, and other programs.

15. NJIT provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New Jersey economy.

Typical Timeline and Processes for NIH Grant Awards

16. The Research Office at NJIT works with researchers to submit grant applications and tracks grant applications and awards.

17. Based on my work as Provost and Senior Vice President for Academic Affairs and as a former Dean, I have an understanding of the NIH grant process based on my 2 years in the Provost role and several years in other leadership roles.

18. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

19. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

20. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

21. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

22. The budget process at NJIT relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within approximately 9 months of submission.

23. Once a grant receives a score, NJIT is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

24. Since late January 2025, NJIT has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

25. NJIT has not received formal notice of changes for many of these grants. For others, NJIT has gotten only a notification that proposals are "paused" or "under review."

26. As of April 11, 2025, NJIT has approximately 40 proposals totaling $70,683,171.27 awaiting NIH study section review.

27. As of April 11, 2025, NJIT has 4 proposals totaling $3,269,729.47 that received fundable scores, awaiting NIH advisory council and Notice of Award.

28. As of April 11, 2025, NJIT has 17 proposals totaling $26,602,999.51 that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

Termination of Grants

29. Since January 20, 2025, NJIT has had 1 NIH grant terminated.

30. The termination received on April 2, 2025 is attached as Exhibit A.

31. This termination will result in a 2024-2025 budgetary loss of $80,053.33, subject to the final close out process, and a loss of $1,227,615 over the remaining future years on the grant. *See* Exhibit B. NJIT has lost an approximate total of $1.3 million in funding.

32. The terminated NIH grant currently supports, in whole or in part, the personnel expenses of 6 faculty and staff members.

U-RISE at the New Jersey Institute of Technology
(NIH Award Number: 5T34GM145521-02)

33. NJIT established a U-RISE program designed to prepare an ethnically diverse group of students for completion of a research-focused higher degree program in a biomedical field. The goals of the program are clearly laid out, trainees complete two summer research experiences, and trainees write and defend a bachelor's thesis. A focus on oral and written communication, an excellent mentor matching strategy, and a student wellness component were also considered strengths. The program is intended to: 1) increase the number of fellowship-supported undergraduate students committed to finishing a Bachelor's Thesis; 2) increase the number of underrepresented groups in research through engagement in self-directed learning-based research experiences; 3) retain trainees for the 3 year training period and graduate within the predicted time to graduation; 4) foster science and engineering identity through asset-based individualized research experiences; 5) increase the number of students who choose to pursue a research-focused higher degree program in a biomedical field, and 6) enhance the visibility and competitiveness of NJIT trainees in the biomedical field.

34. The program comprises didactic training, career development activities, individualized mentorship, and two semesters of research for credit culminating in an undergraduate thesis and scientific dissemination. As an urban technological university serving one of the most ethnically diverse populations in the country, NJIT planned to utilize this training program to prepare a competitive cohort of undergraduate students who, as future scientists and engineers, would help diversify the field of biomedical research. The three-year biomedical research immersion program, focuses on engaging students from all racial and ethnic backgrounds, national origins, gender preferences and abilities. The intended outcomes of U-RISE are to establish a didactic multidisciplinary research training program integrated with academics, enhance the diversity of participation in research, increase competitiveness of trainees, and encourage students to consider an academic or professional degree in the biomedical field (i.e. PhD, MD/PhD).

35. U-RISE aims to combine the strengths of the NJIT Biomedical Engineering, Biological Sciences and Chemistry and Environmental Science Departments to support three undergraduate students per year for three years, or nine students at peak, to participate in a three-year biomedical research immersion program.

36. Through the U-RISE program, 32 well-funded experienced faculty mentors are enlisted for research experiences, mentoring statements are included in faculty bio-sketches, mentor training is required, and the institution provides 1 course release/semester for U-RISE mentors. The publication record of the mentors with their undergraduate students was considered impressive.

37. On April 2, 2025, NJIT received a termination notice from NIH stating that the project "no longer effectuates agency priorities." Exhibit A.

38. The following language was used to justify the termination: "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." Exhibit A.

39. In my time working at NJIT since 2023, I have not seen this language previously used to cancel grants.

40. The termination notice also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. Exhibit A. However, prior to receipt of the termination, NJIT had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was NJIT provided with any updated "agency priorities" with which its research must align.

41. NJIT was awarded a five-year URISE grant by the National Institute of General Medical Sciences on March 23, 2023, which was set to run between April 1, 2023 and March 31, 2028. NJIT was to receive $271,543 for the U-RISE program for the budgetary period of April 1, 2024 through March 31, 2025. At the time of termination, the total amount spent for this project was $191,489.67. Therefore, the funding lost for the 2024-2025 budgetary cycle was $80,053.33, subject to the final close out and adjustment process. NJIT was anticipating $409,205 for each of the remaining three years of the grant covering the 2025-2026, 2026-2027, and 2027-2028 budgetary periods, resulting in a prospective loss of $1,227,615. Exhibit B.

42. This grant was specifically designed to build a skilled biomedical workforce by providing critical research training and mentorship to undergraduate students. The cancellation of this project disrupts the educational trajectory of these students and undermines our institutional efforts to build a robust scientific community. By eliminating these structured research experiences, the NIH's decision directly limits the development of future researchers and innovators, weakening our nation's capacity for scientific discovery and innovation. More specifically, the variety of research directions in which these students would have engaged include the study of traumatic brain injuries, the development of pain biosensors, the study of the neural basis of behavior, the treatment of neuropsychiatric disorders, the treatment of tumors, and the treatment of cardiovascular disease.

Comparisons Across Administrations

43. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

44. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

45. Our ability to forecast and plan for fiscal year 2026 has been disrupted by unreasonable delays by NIH through failure to publish. This has required us to change funding allocations to ensure that critical operations continue in anticipation of continued delay or outright loss of funding.

Admissions, Training and Workforce Disruptions

46. NJIT uses that information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

47. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through pre-doctoral dissertation research (F31 grants).

48. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of NJIT, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

49. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in June. We currently have experienced late NOAs on continued funding and are waiting on one continuing award in particular of $2 million in anticipated funding that is guaranteed based on conversations with the project officer who stated verbally that there is a "backlog" and that there is a "delay in processing" currently. If the timing exceeds the budget timeline, it puts the students' current positions at risk of termination.

50. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time. We have close to 20 proposals pending that have allotted a budget of at least three million dollars each. Half of these are pending study reviews, a third are in a possibly fundable range, and only three still with proposed start dates in the future.

Irreparable Harm

51. NJIT is unable to reallocate funds to offset federal grant award delays and losses in federal grant funding. Federal grant award delays and terminations have disrupted ongoing

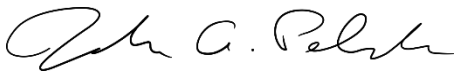
research and will set NJIT back in research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

52. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

53. Absent this critical funding from NIH, NJIT would no longer be able to pursue the research and mentorship programs supported by the U-RISE grant.

Conclusion

54. The breakdown in NIH processes is affecting institutional operations, and planning. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



John A. Pelesko, Ph.D.

Date: 4/12/2025

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

Atam Dhawan
New Jersey Institute of Technology
srard@njit.edu

Dear Atam Dhawan:

Funding for Project Number **5T34GM145521-02** 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 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 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]

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT B

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# T34GM145521
Federal Award Date
03/14/2024

Recipient Information

1. Recipient Name
NEW JERSEY INSTITUTE OF TECHNOLOGY
323 DR MARTIN LUTHER KING JR BLVD
NEWARK, NJ 07102

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226000910A1

4. Employer Identification Number (EIN)
226000910

5. Data Universal Numbering System (DUNS)
075162990

6. Recipient's Unique Entity Identifier
SGBMHQ7VXNH5

7. Project Director or Principal Investigator
Bryan J. Pfister, PHD (Contact)
Associate Professor And Department Chair
pfister@njit.edu
973-596-3401

8. Authorized Official
Dr. Atam P. Dhawan

Federal Agency Information

9. Awarding Agency Contact Information
Adam S Barnhart

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
adam.barnhart@nih.gov
(301) 451-1942

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
5T34GM145521-02

12. Unique Federal Award Identification Number (FAIN)
T34GM145521

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
U-RISE at the New Jersey Institute of Technology

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
Non-Competing Continuation

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	$271,543
20 a. Direct Cost Amount	$258,540
20 b. Indirect Cost Amount	$13,003
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$271,543
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$271,543
26. Project Period Start Date 04/01/2023 **– End Date** 03/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$409,205

28. Authorized Treatment of Program Income
Other Research (Add/Deduct Option)

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.

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Notice of Award

MARC NATIONAL RESEARCH SERVICE AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 5T34GM145521-02

Principal Investigator(s):
Ashish D Borgaonkar
Bryan J. Pfister (contact), PHD
OMOWUNMI A SADIK, PHD
DAPHNE SOARES, PHD
Prateek Shekhar

Award e-mailed to: srard@njit.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $271,543 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to NEW JERSEY INSTITUTE OF TECHNOLOGY 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 T34GM145521. 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

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Stipends	$86,040
Tuition & Fees	$96,000
Trainee Travel	$16,500
Training related Expenses	$60,000
Federal Direct Costs	$258,540
Federal F&A Costs	$13,003
Approved Budget	$271,543
Total Amount of Federal Funds Authorized (Federal Share)	$271,543
TOTAL FEDERAL AWARD AMOUNT	$271,543
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$271,543

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$271,543	$271,543
3	$409,205	$409,205
4	$409,205	$409,205
5	$409,205	$409,205

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1226000910A1
Document Number:	TGM145521A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026	2027
GM	8472205	$271,543	$409,205	$409,205	$409,205

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: T412SJ / **OC**: 41013 / **Released**: Rosenzweig, Justin 03/13/2024
Award Processed: 03/14/2024 12:16:11 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5T34GM145521-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5T34GM145521-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htmfor certain references cited above.)

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) T34GM145521. 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

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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:
Other Research (Add/Deduct Option)

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 5T34GM145521-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

1. This grant must be administered in accordance with the guidelines and restrictions described in the Initiative for Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program announcement PAR-21-146 available at: https://grants.nih.gov/grants/guide/pa-files/PAR-21-146.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 Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program as well as answers to Frequently Asked Questions, please visit: https://www.nigms.nih.gov/training/RISE

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-23-076 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-076.html)

4. SUMMER RESEARCH EXPERIENCE: This award includes $10,500 to support the Summer Research Experience (SRE) for 50% of the total trainee slots awarded. These funds are based on $3,000 per trainee slot for per diem expenses for ten weeks and $500 for travel plus 8% F&A costs. They are restricted solely for this purpose and may not be rebudgeted into other categories. Additionally, funds have been included in future years for this purpose. Travel to foreign sites (a country other than the United States and its territories) is not allowed for any trainee while appointed to the grant. Please review the SRE guidelines posted at https://www.nigms.nih.gov/training/T34/Pages/sre.aspx

5. 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.

6. This award includes funds to support six (6) trainees (72 Trainee Months). The maximum number of trainees that may be appointed without the prior written approval of NIGMS staff is 10 (120 Trainee Months) if funds are available through rebudgeting.

7. Although future years include a recommended number of trainee positions, actual award levels are contingent upon availability of funds. In general, grantees should

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NOT expect an increase in the actual number of slots awarded in future years unless notified by institute program staff.

8. In accordance with NIH Guide Notice NOT-OD-10-072, appointment documentation 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

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. Failure to submit documentation may result in an expenditure disallowance or a delay in continued funding.

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.

9. 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.

10. The next non-competing progress report for this grant is due on August 15, 2024.

11. 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

12. 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.

13. In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

NIGMS' OFFICIAL WEBSITE

The NIGMS WWW home page is at http://www.nigms.nih.gov

SPREADSHEET SUMMARY
AWARD NUMBER: 5T34GM145521-02

INSTITUTION: NEW JERSEY INSTITUTE OF TECHNOLOGY

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EXHIBIT 53

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

SUPPLEMENTAL DECLARATION OF JOHN J. FARMER, JR.

I, John J. Farmer, Jr., upon information and belief, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the following is true and correct:

1. I am the Interim Senior Vice President and General Counsel of Rutgers, the State University of New Jersey.

2. I have compiled the information in the statements set forth below through review of Rutgers's records and other documents gathered by Rutgers personnel who have assisted me and on the basis of documents that have been provided to and/or reviewed by me in order to understand their immediate impact on Rutgers.

3. On April 4, 2025, I provided a declaration (ECF Docket No. 12-20) in support of Plaintiff's Motion for a Temporary Restraining Order, which is now set to be heard as a Motion for Preliminary Injunction.

4. I submit both my original declaration (ECF Docket No. 12-20) and this supplemental declaration in support of Plaintiff's Motion for a Preliminary Injunction.

A. Professional Background

5. I am the Interim Senior Vice President and General Counsel at Rutgers, the State University of New Jersey. I have served in this capacity since 2024. I am the chief counsel for the University. Previously, I have served as Dean of Rutgers School of Law and Director of the Eagleton Institute. From 1999-2002, I was Attorney General of the State of New Jersey.

B. The Rutgers University System

6. Founded in 1766, Rutgers is the oldest, largest, and highest-ranked public university in the New York/New Jersey Metropolitan area and is among the nation's highest- ranked public research universities.

7. As New Jersey's land-grant university, Rutgers has a significant academic and clinical health sciences presence across the state, including activity in each of the State's 21 counties and three campuses located in the cities of Camden, Newark, and New Brunswick, New Jersey.

8. In addition to providing higher education to students from New Jersey and across the nation, Rutgers also supports significant medical and behavioral research and clinical trials across its colleges and schools. Rutgers conducts vital research across a wide range of areas including heart disease, cancer, neuroscience and brain health, and infectious disease.

C. Reliance on National Institutes of Health Funding

9. To fund these crucial medical research programs, Rutgers is the recipient of federal funding, including annual funding from the National Institutes of Health ("NIH") totaling approximately $250 million. NIH funding at Rutgers currently supports nearly 1,200 separate grants and more than 2,200 employees.

10. In fiscal year 2024, Rutgers received funding through the NIH to support approximately 1,200 projects, totaling approximately $250 million.

11. Rutgers receives NIH grants across a variety of institutes encompassed within the

NIH, including but not limited to the National Institutes on Aging, National Institute on Minority Health and Health Disparities, National Heart Lung and Blood Institute, National Institute of Allergy and Infectious Diseases, National Cancer Institute and the National Institute of General Medical Sciences.

12. Through those NIH grants, Rutgers funds over 2,400 faculty and staff positions in whole or in part.

13. Rutgers provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New Jersey economy.

D. Typical Timeline and Processes for NIH Grant Awards

14. The Research and Sponsored Programs unit of the Office for Research at Rutgers works with researchers to submit grant applications and tracks grant applications and awards.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute/center, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-Center for Scientific Review) will only result in an impact score, but not a percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a

percentile less than 10% as extremely likely to receive funding

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at Rutgers relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 9 months of submission.

20. Once a grant receives a score, Rutgers is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

E. Delays and Irregularities in the Processing of NIH Grant Applications

21. Since late January 2025, Rutgers has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

22. Rutgers has not received formal notice of changes for any of these grants. For many grants, Rutgers researchers have gotten only informal notice of delays through phone calls or emails from their program officers.

23. As of April 11, 2025, Rutgers has approximately 13 proposals totaling $26,990,860 awaiting NIH study section review.

24. As of April 11, 2025, Rutgers has approximately six proposals totaling $19,608,265 that received fundable scores, awaiting NIH advisory council review and Notice of Award.

25. Additionally, as of April 11, 2025, Rutgers currently has 738 grant submissions under

sponsor review with a total value of $1,387,066,143.

26. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

27. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

28. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

F. Terminations of NIH Grants

29. In addition to the four NIH grants discussed in my April 4, 2025 declaration, Rutgers has had two additional NIH grants terminated as of April 10, 2025.

30. The termination letters and notices of awards concerning these two additional terminated grants are attached hereto as Exhibits A through D.

31. 2025 funding lost in connection with these grants is $514,303.53, subject to the final close out and adjustment process.

32. As such, the 2025 budgetary loss across all six terminated grants, including the four grants identified in my April 4, 2025 Declaration (ECF Docket No. 12-20), is $2,480,345.97. The anticipated losses across all six terminated grants in future years total $4,580,826. Collectively, Rutgers has lost more than $7 million in funding.

33. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities."

34. The termination notices have also stated that there is "no corrective action" that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, Rutgers had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities despite policy guidance from NIH that "NIH generally will suspend (rather

than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision." 2024 NIH Grants Policy Statement at IIA-156. Nor was Rutgers provided with any updated "agency priorities" with which its research must align.

Addressing HPV Vaccination Disparities Through Tailored Messaging for Hesitant Families (NIH Award Number: 5K22CA258675-03)

35. NIH also terminated grant funding for a study by Rutgers Biomedical and Health Sciences researchers on developing improved strategies to reduce HPV vaccine hesitancy and, in turn, increase vaccine confidence, vaccination, and reduce HPV-related cancer disparities, Award Number 5K22CA258675-03, on April 1, 2025. Exhibit A. The Notice of Award ("NOA") for this grant is attached as Exhibit B. The project received its funding from the National Cancer Institute ("NCI") in response to a Funding Opportunity Announcement, PAR-18-466, which was aimed at facilitating the transition of investigators in mentored, non-independent cancer research positions to independent faculty cancer research positions.

36. NCI leads a national effort to eliminate the suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research that will lead to a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

37. The grant was awarded on August 2, 2022, and was intended to fund research faculty and staff as well as vaccine counseling services. One faculty member and one staff member are affiliated with this project. Exhibit B.

38. This grant provided three years of funding and is scheduled to terminate on July 31, 2025. The total amount of funding was $659,697 over that three-year period. At the time of

termination, the total amount spent for this project was $541,767.47. Therefore, the funding lost in 2025 was $117,929.53, subject to the final close out and adjustment process. Exhibit B. The reason given for termination was, "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." See Exhibit A. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

39. The termination of this funding results in irreparable harm. The grant termination resulted in a loss of funding for salaries. Additionally, this grant supported many community services that are now halted. A trial involving tailored HPV counseling ceased. The grant also supports HPV vaccination education and outreach efforts in pediatric facilities, schools, and family-friendly spaces, which has ended. Furthermore, grant funding helped connect low-income families with adolescents to the New Jersey Vaccine for Children program, which is also now suspended.

Initiative for Maximizing Student Development
(NIH Award Number: 5T32GM139804-05)

40. NIH also terminated the grant funding for the Initiative for Maximizing Student Development ("IMSD") program at Rutgers, Award Number 5T32GM139804-05, on April 2, 2025. Exhibit C. The NOA for this grant is attached as Exhibit D. The project received its funding from the National Institute of General Medical Sciences ("NIGMS") in response to a Funding Opportunity Announcement, PAR-19-037, which was aimed at developing a diverse pool of Ph.D. scientists with the skills to successfully transition into biomedical research careers.

41. NIGMS supports basic research that increases our understanding of biological

processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS also supports research in specific clinical areas that affect multiple organ systems: anesthesiology and peri-operative pain; clinical pharmacology common to multiple drugs and treatments; and injury, critical illness, sepsis, and wound healing. NIGMS-funded scientists investigate how living systems work at a range of levels—from molecules and cells to tissues and organs—in research organisms, humans, and populations. Additionally, to ensure the vitality and continued productivity of the research enterprise, NIGMS provides leadership in supporting the training of the next generation of scientists, broadening participation in the scientific workforce, and developing research capacity throughout the country.

42. The grant was awarded on January 17, 2025, and was intended 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. 9 predoctoral students receive stipends funded by this grant. This grant is scheduled to terminate on January 31, 2026.

43. This grant provided one year of funding totaling $362,537, plus an offset of unobligated funds in a previous budget period worth $103,788, for a total of $466,325. At the time of termination, the total amount spent for this project was $69,951.84. Exhibit D. Therefore, the funding lost in 2025 was $396,374, subject to the final close out and adjustment process. The reason given for termination was that termination was due to “changes in NIH/HHS priorities.” See Exhibit C. Rutgers researchers were not referred to any new policy statement or regulation that described the new agency priorities.

G. Impacts from NIH Funding Terminations and Delays and Irreparable Harm

44. Rutgers will be unable to reallocate funds to offset these delays and losses in federal grant funding. Alternative sources of funding are unavailable such that Rutgers faculty and researchers will be forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment, and who may also face deportation as a result of a loss of sponsored visas;

c. Stop ongoing experiments, compromising time-sensitive components of the research;

d. Pause community-based partnerships, disrupting services; and

e. Delay work on clinical translation, including potential therapeutic development.

45. Students working in these labs who are relying on research conducted there to obtain their Ph.D. will see delays in their progression and career development.

46. Shared research core facilities will need to lay off staff and close.

47. These delays will cause slowdowns or pauses in hiring new faculty and staff.

H. Comparisons Across Administrations

48. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

49. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

50. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

I. Admissions, Training and Workforce Disruptions

51. Rutgers may need to reduce the number of undergraduate and graduate students admitted.

52. NIH training grants, including T32 and F31 mechanisms, will be affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants).

53. The visa status of international postdocs will be at risk due to pending NIH awards that were expected to renew this spring.

J. Irreparable Harm

54. The delays have disrupted and will disrupt ongoing research, as well as setting back Rutgers for research going forward. Funding gaps will force researchers to abandon studies, miss deadlines, or lose key personnel.

55. Impacts to studies involving clinical trials for life-saving medications or procedures, and their closure could endanger the lives of patients.

56. Some of these studies may have the potential to achieve breakthroughs which would have advanced public health, and which may not occur.

57. Delays will also disrupt community services, student opportunities, and public programs.

58. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

59. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and irreparable.

Signed by:
6BAC825D7E72438...

John J. Farmer, Jr.
Interim Senior Vice President and General Counsel Rutgers, The State University of New Jersey

Date: 4/12/2025

EXHIBIT A

Outlook

FW: Grant Termination Notification

From Latona Thompson <thompslm@ored.rutgers.edu>
Date Tue 4/1/2025 4:17 PM
To federal-tracking@rutgers.edu <federal-tracking@rutgers.edu>
Cc Latona Thompson <thompslm@research.rutgers.edu>

I just received the email below for AWD00010466 Racquel Kelly Kohler (CINJ).

Thanks

Latona

Future out of Office dates
April 30th, May 23rd, May 27th and June 19th.
****

RUTGERS UNIVERSITY Office for Research

Latona Thompson, MPA
Authorized Organizational Representative (AOR)
Senior Research Contract/Grants Specialist
Research and Sponsored Programs
33 Knightsbridge Road, 2nd Floor East, E230D, Piscataway, NJ 08854

phone: (848) 932-4054 | email: thompslm@research.rutgers.edu

research.rutgers.edu | Follow @RutgersResearch

"Your smile is your logo, your personality is your business card, how you leave others feeling after having an experience with you is your trademark!"

Legal Disclaimer: The information in this message is intended only for the person(s) addressed. This message may contain proprietary, confidential, and/or privileged material not meant to be shared with third parties. If this message was not intended for you, then you received it in error. Please contact me and delete the email. I apologize for the inconvenience.

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Tuesday, April 1, 2025 9:24 AM
To: Latona Thompson <thompslm@ored.rutgers.edu>
Subject: Grant Termination Notification

NIH National Institutes of Health
Office of Extramural Research

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)

EXHIBIT B

Department of Health and Human Services
National Institutes of Health
NATIONAL CANCER INSTITUTE

Notice of Award
FAIN# K22CA258675
Federal Award Date
08-02-2022

Recipient Information

1. Recipient Name
RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST

NEWARK, 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

6. Recipient's Unique Entity Identifier
YVVTQD8CJC79

7. Project Director or Principal Investigator
Racquel Elizabeth Kohler, PHD

kelly.kohler@rutgers.edu
732-258-6031

8. Authorized Official
Latona M Thompson

Federal Agency Information

9. Awarding Agency Contact Information
Nailah Agyemann
Grants Technical Assistant
NATIONAL CANCER INSTITUTE
agyemann@mail.nih.gov
(240) 276-6290

10. Program Official Contact Information
SONIA B JAKOWLEW
Program Director
NATIONAL CANCER INSTITUTE
jakowles@mail.nih.gov
240-276-5630

Federal Award Information

11. Award Number
1K22CA258675-01A1

12. Unique Federal Award Identification Number (FAIN)
K22CA258675

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Addressing HPV vaccination disparities through tailored messaging for hesitant families

15. Assistance Listing Number
93.398

16. Assistance Listing Program Title
Cancer Research Manpower

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 08-02-2022 **– End Date** 07-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$219,899
20 a. Direct Cost Amount	$203,610
20 b. Indirect Cost Amount	$16,289
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$219,899
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$219,899
26. Project Period Start Date 08-02-2022 **– End Date** 07-31-2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$219,899

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Carey Beckley

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

ACADEMIC CAREER AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL CANCER INSTITUTE

SECTION I – AWARD DATA – 1K22CA258675-01A1

Principal Investigator(s):
Racquel Elizabeth Kohler, PHD

Award e-mailed to: rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $219,899 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number K22CA258675. 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,

Carey Beckley
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$100,000
Fringe Benefits	$53,610
Personnel Costs (Subtotal)	$153,610
Other	$50,000
Federal Direct Costs	$203,610
Federal F&A Costs	$16,289
Approved Budget	$219,899
Total Amount of Federal Funds Authorized (Federal Share)	$219,899
TOTAL FEDERAL AWARD AMOUNT	$219,899
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$219,899

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$219,899	$219,899
2	$219,899	$219,899
3	$219,899	$219,899

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1226001086A1
Document Number:	KCA258675A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024
CA	8481719	$219,899	$219,899	$219,899

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: 1STR / **OC**: 41033 / **Released**: Beckley, Carey 08-01-2022
Award Processed: 08/02/2022 12:04:51 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1K22CA258675-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1K22CA258675-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) K22CA258675. 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/

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 – CA SPECIFIC AWARD CONDITIONS – 1K22CA258675-01A1

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.

REQUIREMENT: This award is subject to the conditions set forth in PAR 18-466, "The NCI Transition Career Development Award (K22 Independent Clinical Trial Required)," NIH Guide to Grants and Contracts, (12/06/2017), which are hereby incorporated by reference as special terms and conditions of this award.

Copies of this funding opportunity announcement may be accessed at: http://www.nih.gov/grants/guide/index.html

Copies may also be obtained from the Grants Management Contact indicated in the terms of award.

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.

REQUIREMENT: Recipients of a National Cancer Institute Transition Career Development Award (K22) must apply for National Institutes of Health or other independent research project grant support for peer review and funding consideration prior to the end of the second year of support.

REQUIREMENT: The clinical trial(s) supported by this award is subject to the plan dated 07/15/2022 submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

REQUIREMENT: This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under

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this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

REQUIREMENT: The awardee 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 National Cancer Institute.

INFORMATION: This award involves Human Subjects Research. See "Assurance Requirements and Institutional Review Boards" under Part II, Subpart A, Human Subjects, in the NIH Grants Policy Statement, for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award.

This award reflects the National Cancer Institute's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with the NIH Grants Policy Statement, "Education in the Protection of Human Research Subjects."

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: Although the budget period start date for this award is 08/02/2022, this award includes funds for twelve months of support. Future year budget periods will cycle on 08/01. Allowable pre-award costs may be charged to this award, in accordance with the conditions in the NIH Grants Policy Statement, and with institutional requirements for prior approval.

INFORMATION: This award, including the budget and the budget period, has been discussed between Nailah Agyemann of the National Cancer Institute and Latona Thompson on 08/01/2022.

SPREADSHEET SUMMARY
AWARD NUMBER: 1K22CA258675-01A1

INSTITUTION: RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 1	Year 2	Year 3
Salaries and Wages	$100,000	$100,000	$100,000
Fringe Benefits	$53,610	$53,610	$53,610
Personnel Costs (Subtotal)	$153,610	$153,610	$153,610
Other	$50,000	$50,000	$50,000
TOTAL FEDERAL DC	$203,610	$203,610	$203,610
TOTAL FEDERAL F&A	$16,289	$16,289	$16,289

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TOTAL COST	$219,899	$219,899	$219,899

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	8%	8%	8%
F&A Cost Base 1	$203,610	$203,610	$203,610
F&A Costs 1	$16,289	$16,289	$16,289

EXHIBIT C

From: Gibbs, Kenneth (NIH/NIGMS) [E]
To: Cathy Rivera
Subject: NIGMS Funding Update
Date: Wednesday, April 2, 2025 1:24:23 PM

Re: GM139804-05

Dear Wendy Neil,

As business official for the above referenced award, I am writing to let you know that due to changes in NIH/HHS priorities, the **Initiative for Maximizing Student Development (IMSD)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT D

Docusign Envelope ID: D4017E02-8003-4172-A1A6-8A250BCB5DAE

National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# T32GM139804
Federal Award Date
01/17/2025

Recipient Information

1. Recipient Name
RUTGERS THE STATE UNIVERSITY OF NEW JERSEY
65 BERGEN ST
STE 1
NEWARK, NJ 07107

2. Congressional District of Recipient
10

3. Payment System Identifier (ID)
1226001086A1

4. Employer Identification Number (EIN)
226001086

5. Data Universal Numbering System (DUNS)
090299830

6. Recipient's Unique Entity Identifier
YVVTQD8CJC79

7. Project Director or Principal Investigator
LOREN W RUNNELS, PHD (Contact)
Associate Professor
runnellw@rwjms.rutgers.edu
732-235-4593

8. Authorized Official
Wendy Neil
wn82@rutgers.edu
856-225-6645

Federal Agency Information

9. Awarding Agency Contact Information
Jessica Dean

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
deanje@mail.nih.gov
(301) 451-2447

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
5T32GM139804-05

12. Unique Federal Award Identification Number (FAIN)
T32GM139804

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
IMSD at Rutgers - New Brunswick

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2025 **– End Date** 01/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$362,537
20 a. Direct Cost Amount	$440,676
20 b. Indirect Cost Amount	$25,649
21. Authorized Carryover	$0
22. Offset	$103,788
23. Total Amount of Federal Funds Obligated this budget period	$362,537
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$362,537
26. Project Period Start Date 02/01/2021 **– End Date** 01/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,382,151

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Leslie Nichols

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

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Notice of Award

NATIONAL RESEARCH SERVICE AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 5T32GM139804-05

Principal Investigator(s):
JAMES H. MILLONIG, PHD
LOREN W RUNNELS (contact), PHD
Tracy E Scott, PHD

Award e-mailed to: rsp-rbhs@research.rutgers.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $362,537 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RUTGERS BIOMEDICAL AND HEALTH SCIENCES in support of the above referenced project. This award is pursuant to the authority of 42 USC 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 T32GM139804. 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,

Leslie Nichols
Grants Management Officer
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Childcare Costs	$27,000

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Stipends	$254,016
Tuition & Fees	$93,060
Trainee Travel	$9,000
Training related Expenses	$57,600
Federal Direct Costs	$440,676
Federal F&A Costs	$25,649
Approved Budget	$466,325
Total Amount of Federal Funds Authorized (Federal Share)	$362,537
Cumulative Authorized Carryover and Offset for this Budget Period	$103,788
TOTAL FEDERAL AWARD AMOUNT	$362,537
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$362,537

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**
5	$362,537	9			$362,537	9		

Fiscal Information:

Payment System Identifier:	1226001086A1
Document Number:	TGM139804B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025
GM	8039713	$362,537

NIH Administrative Data:
PCC: T417JM / **OC**: 41013 / **Released**: 01/16/2025
Award Processed: 01/17/2025 12:09:04 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5T32GM139804-05

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 – 5T32GM139804-05

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

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report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) T32GM139804. 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

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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

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 5T32GM139804-05

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.

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-19-037) available at: https://grants.nih.gov/grants/guide/pa-files/PAR-19-037.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

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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. This award represents the final year of the competitive segment for this grant. If the grant is extended, only trainees currently supported may be reappointed during the extension period. No new trainees may be appointed during this period.

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. 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.

6. This award includes funds to support 9 trainees (108 Trainee Months). The maximum number of trainees that may be appointed without the prior written approval of NIGMS staff is 10 (120 Trainee Months) if funds are available through rebudgeting.

7. 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)

8. 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

9. 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.

10. In keeping with NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grantee institution must secure and retain the signatures of all of the PIs within their own internal processes.

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11. This award reflects use of an unobligated balance of $103,788 based on the year 3 Federal Financial Report (FFR). Although this award reflects an adjustment, this is not a decrease in funding for the project. Total funding for this project continues to be indicated as the “Approved Budget” in Section I of the Notice of Award.

NIGMS’ OFFICIAL WEBSITE
For more information, please visit: http://www.nigms.nih.gov

SPREADSHEET SUMMARY
AWARD NUMBER: 5T32GM139804-05

INSTITUTION: RUTGERS BIOMEDICAL AND HEALTH SCIENCES

Budget	Year 5
Childcare Costs	$27,000
Stipends	$254,016
Tuition & Fees	$93,060
Trainee Travel	$9,000
Training related Expenses	$57,600
TOTAL FEDERAL DC	$440,676
TOTAL FEDERAL F&A	$25,649
TOTAL COST	$362,537

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	8%
F&A Cost Base 1	$320,616
F&A Costs 1	$25,649

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EXHIBIT 54

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814-BEM

DECLARATION OF LAKSHMI REDDI, PHD

I, Lakshmi Reddi, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Provost of New Mexico State University (NMSU). I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with the New Mexico State University staff, or from documents made in the regular course of business that have been provided to and reviewed by me, and if required to testify, would and could competently do so.

2. I submit this Declaration in connection with *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, No. 1:25-cv-10814.

Professional Background

3. I am the Interim Provost at New Mexico State University. I previously served as the Dean of the College of Engineering for over eight years. As Provost, I oversee the deans of the colleges participating in the vital research activities at NMSU. I have a background as an

administrator, professor, and research principal investigator and am familiar with research matters at NMSU. I hold a PhD of Civil Engineering.

4. New Mexico State University's statutory mission is to serve the diverse needs of the state through comprehensive programs of education, research, extension and outreach, and public service. As the state's land-grant and space-grant university, and as a Hispanic-Serving Institution, NMSU fosters learning, inquiry, diversity and inclusion, social mobility, and service to the broader community.

5. New Mexico State University is an R1 research institution with research centers statewide, including vital research in the areas of molecular, chemistry, and biochemistry projects. NMSU offers graduate programs in molecular biology and interdisciplinary life sciences and STEM programs. NMSU has A list of NMSU's research facilities may be accessed at https://research.nmsu.edu/ResearchFacilities.html .

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

Reliance on NIH Funding

7. In fiscal year 2024, New Mexico State University received funding through the National Institutes of Health ("NIH") to support projects, totaling over $10,000,000.

8. New Mexico State University receives NIH grants across a variety of institutes encompassed within the NIH, including National Institute of General Medical Sciences (NIGMS), National Cancer Institute (NCI), and National Institute on Alcohol Abuse and Alcoholism (NIAAA).

9. Through those NIH grants, New Mexico State University funds more than thirty researchers.

10. The work done by New Mexico State University on NIH funded projects provides education and training in Biomedical Engineering, Chemical Engineering, Civil Engineering, Electrical Engineering, Mechanical Engineering, Agriculture, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, and other programs.

11. New Mexico State University provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the New Mexico economy.

Typical Timeline and Processes for NIH Grant Awards

12. The office of Research Administration Services (RAS) at New Mexico State University works with researchers to submit grant applications and tracks grant applications and awards.

13. Based on my work as Interim Provost and as Dean, I have an understanding of the NIH grant process based on my approximately 11 years in the roles.

14. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

15. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

16. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

17. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

18. The budget process at New Mexico State University relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within three months of submission.

19. Once a grant receives a score, New Mexico State University is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

20. Since late January 2025, New Mexico State University has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

21. New Mexico State University has not received formal notice of changes for many of these grants. For others, New Mexico State University has gotten only a notification that proposals are "paused" or "under review."

Terminations of NIH Grants

22. Since April 2, 2025, New Mexico State University has had three NIH grants terminated.

23. The terminations received as of April 2, 2025 are attached hereto as Exhibits.

24. These terminations will result in the loss of $6,700,000.00 in research money to New Mexico State University.

25. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my more than ten years working at New Mexico State University, I have not seen this language previously used to cancel grants.

Comparisons Across Administrations

26. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

27. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

28. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

29. Several shared research cores have seen decreased usage due to grant uncertainty, and one facility temporarily reduced staff hours due to budget delays.

Concerns About FY25 Funds Being Obligated

30. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

31. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

32. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

33. The delays have disrupted ongoing research, as well as setting back New Mexico State University for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

34. Delays have also disrupted student opportunities.

35. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

36. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

Lakshmi Reddi

Lakshmi Reddi, Provost

Date: April 13, 2025

EXHIBIT 55

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814-BEM

DECLARATION OF SHELLEY L. LUSETTI, PH.D.

I, Shelley L. Lusetti, Ph.D., declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Director of the New Mexico IDeA Networks of Biomedical Research Excellence of New Mexico State University. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in connection with *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, No. 1:25-cv-10814.

Professional Background

3. I am a Professor of Biochemistry at New Mexico State University. I have been on the faculty of New Mexico State University since 2006. I am also the department head of Chemistry and Biochemistry. I earned my Bachelor of Science in Biology from the University of California-Santa Barbara and my Ph.D. in Biochemistry form the University of Wisconsin-Madison. My research program focuses on the enzymology of DNA repair and has been funded by the National Institutes of Health and the National Science Foundation. Since 2016, I have been

the Principal Investigator and Program Director for the New Mexico IDeA Networks of Biomedical Research Excellence (NM-INBRE) that seeks to builds biomedical research infrastructure throughout the state of New Mexico.

4. I lead a large programmatic grant (NM-INBRE) focused on building research infrastructure, training undergraduate and graduate students for the biomedical workforce, and supporting junior faculty in developing competitive biomedical reseach labs across 10 institutions in the state of New Mexico. The grant is hosted at New Mexico State University. I have served as a Principal Investigator (PI) or Co-Investigator on numerous National Institutes of Health ("NIH") funded projects over the course of my career. I have also served on several special emphasis study sections and the Training and Workforce Developent Section D study section, which are study sections focused on programmatic, workforce development grants. I have one active grant related to research infrastructure and workforce development.

5. I am providing this declaration to detail my experience in applying for and reviewing NIH grant applications, as well as with renewals and terminations of NIH-funded grants historically, and how that experience has changed since late January of 2025.

6. I am also providing this declaration to explain the impacts of delays in the grant review and renewal process and of grant terminations on my staff, my research, and the people who benefit from it.

7. The delay in grant review, renewals, and terminations severely impacts me and my program by jeopardizing the paid summer internships of 50 undergraduate students, the research funding of 20 research projects across the state, including research, for example, on clinically relevant diabetes mechanisms to research on basic mechanisms of membrane transport, and the salaries of full-time and part-time staff and graduate students.

Reliance on NIH Funding

8. In fiscal year 2024, my program received funding through NIH to support the network projects, totaling $5,061,077. I received these funds under one grant with two additional supplements, which run from April 1, 2024 through March 31, 2029.

9. My program employs twenty workers who are funded primarily through NIH grants, whose employment I will have to terminate if my grant is terminated. There are also fifteen PhD students who work on projects funded through the program and rely primarily on the NIH award, and who are relying on the work done there to complete their own research and earn their degrees, and who could not continue to do so absent NIH funding. Further, there are 50 undergraduate student interns that will lose their summer salaries and the training opportunity from their internship absent NIH funding.

Typical Timeline and Processes for NIH Grant Awards

10. For NIH grants, the first step in the process is typically a Notice of Funding Opportunity ("NOFO"), which may be a broad call for investigator-initiated proposals, or a more specific notice related to topics of emphasis. Some of these establish specific due dates, but for most there are standard deadlines based on the type of grant at issue. The standard due dates align with three annual review and funding cycles. For example, for research grants the standard due dates fall in February, June, and October.

11. Grant applications are typically submitted via NIH's online portal, which also allows the applicant to track the status of the grant, and provides access to scores and summaries generated by study sections and advisory councils.

12. Study sections and advisory council meetings are typically scheduled to align with these three funding cycles, with numerous study sections held in each cycle prior to advisory council meetings.

13. As a reviewer on a study section, I am typically assigned 8-10 grants to review. This is an intensive and rigorous process, which typically takes 8 hours of my time for each grant in advance of the study section meeting. To be able to effectively present and discuss each of my assigned grants at the study section meeting, I typically need to conduct my review shortly before the meeting occurs. After reviewing the grant at the study section, we provide each with a score. This score, along with a summary statement that summarizes the discussion, is provided to the applicant as well as the advisory council.

14. Through the peer review process, grant applications are given a score and sometimes assigned a percentile as well. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded. What constitutes a fundable score is dependent on several factors as every institute or center, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. I would consider a percentile less than 10% as highly likely to receive funding.

15. Once a grant is awarded, the applicant receives a Notice of Award, specifying the conditions of the grant and the amount of funding. Grants are typically awarded for 3-5 year terms, though some may be longer and others may be shorter.

16. Although the life of the grant is often longer, funding is only provided on an annual basis, and grants must be renewed annually. This is typically done through a non-competitive renewal, which requires a report on progress on the grant project. These non-competing renewals

do not go through a new review process involving study sections and advisory councils. If funding is available and progress is being made on the state project goals, in my experience such renewals are typically granted.

17. These regular cycles and predictable renewals are essential for the continuity of funding for my program. This allows for the program to identify new projects each year, set up sub-contracts to the ten partner institutions across the state of New Mexico, and to follow a set application, review, and award process for our summer interns.

18. In my experience, termination of an active grant is extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Delays and Irregularities in the Processing of NIH Grant Applications

19. Since late January 2025, I have seen an unusual number of delays in processing my grant applications, as well as in the grant review process in which I participate as a reviewer.

20. For example, in the current year I submitted the progress report for our grants continuation, for which the non-competetive renewal remains pending. In prior years, I would have expected to receive confirmation of funding for my renewal by March 15th. Based on our outcomes, this would have left me with time to prepare awards for the students, faculty, and institutions in the network before the start date of April 1. However, this year, despite multiple inquiries, I have not received any formal communication explaining the delay.

21. I have been unable to obtain any substantive update from NIH staff regarding where my continuing application stands in the process. In the past, I have consistently received timely communications from NIH regarding my applications.

Irregularities in Grant Terminations

22. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research, research training, and the dissemination of health information, and that the National Institute of General Medical Science's role is "to supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS-funded scientists investigate how living systems work at a range of levels—from molecules and cells to tissues and organs—in research organisms, humans, and populations. Additionally, to ensure the vitality and continued productivity of the research enterprise, NIGMS provides leadership in supporting the training of the next generation of scientists and developing research capacity throughout the country." My NM-INBRE program advances those goals by building research infrastructure, directly funding cutting-edge research in biomedical sciences, and training undergraduate and graduate students to develop the future workforce of biomedical researchers across the state of New Mexico.

Comparisons Across Administrations

23. In prior years, under both Democratic and Republican administrations, I have submitted similar numbers of grant applications and received timely responses and awards. I have never experienced these types of unexplained delays or procedural breakdowns that have occurred within the last three months.

24. Since late January, the tone and responsiveness of NIH communications have changed significantly. Based on my communications with NIH staff, there now appear to be a growing number of topics that face internal scrutiny, without regard to their scientific merit. As a result, applications are being pulled from the review process without explanation, renewals are stalled, and terminations are being issued based on unexplained agency priorities. I have never

experienced this internal scrutiny or stalling of awards, in either Republican or Democratic administrations.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

25. Due to the delays and funding uncertainty, and having sought alternative sources of funding and failed to secure them, in the next month, I will be forced to:

a. Suspend hiring and reduce research staff hours, which risks the loss of key lab and program personnel who may be forced to seek other employment due to these cuts;

b. Terminate employment of research staff, who will be forced to seek other employment, and who may also face deportation as a result of a loss of sponsored visas;

c. Stop ongoing experiments, compromising time-sensitive components of several research studies including the loss of animal models and other research samples.

d. Pause community-based partnerships, disrupting services such as the training of community health researchers.

e. Cancel the 2025 summer internship program for undergraduate students.

26. Students working in the labs funded by my program who are relying on research conducted there to obtain their PhDs are likely to see years of delay in their progression and career development. Undergraduate students relying on the summer internships with lose a critical source of summer support and set back their training.

27. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

28. The breakdown in NIH processes is affecting my program, my staff, the research of 20 faculty funded by my program, and those individuals who stand to benefit from the research and the infrastructure that my program provides. Terminations and delays with no explanation or remedy are undermining my confidence in the system, making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.

/s/ Shelley L. Lusetti, Ph.D.
Shelley L. Lusetti, Ph.D.

Date: April 13, 2025

EXHIBIT 56

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF MICHAEL E. RICHARDS, M.D., MPA

I, Michael E. Richards, M.D., MPA, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Executive Vice President for Health Sciences and Chief Executive Officer of the UNM Health System of the Regents of the University of New Mexico ("UNM" or "the University"). I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so. The records to which I refer in this Declaration were made at or near the time of the event by someone with knowledge and have been provided to and reviewed by me; the records were kept in the course of a regularly conducted activity of UNM, and the making of those records was a regular practice of those activities.

2. I submit this Declaration in connection with *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, No. 1:25-cv-10814.

Professional Background

3. As Executive Vice President for Health Sciences and Chief Executive Officer of the UNM Health System, I have administrative responsibility for all activities, operations, and

programs of the UNM Health Sciences Center, including the UNM Health System. I serve as the chief academic officer relative to colleges, schools, programs, and centers at the UNM Health Sciences Center. I oversee the deans of the UNM School of Medicine, the UNM College of Pharmacy, the UNM College of Nursing, and the UNM College of Population Health and the work of the faculty in the colleges, schools, programs, and centers at the UNM Health Sciences Center. Previously, I have had a background as both an administrator and physician, having most recently served as Senior Vice President for Clinical Affairs, the Interim Executive Vice President of UNM Health Sciences, Interim Dean of the UNM School of Medicine, and as a professor and former chair of the Emergency Medicine Department as well as former Chief of Staff at UNM Hospital. I received my medical training at the Brody School of Medicine at East Carolina University and a master of public administration at the University of North Carolina. I completed my internship and residency in emergency medicine at UNM.

4. UNM is a state educational institution established in Article XII, Section 11 of the New Mexico Constitution. UNM is the flagship university in the State of New Mexico. UNM is the home of the UNM Hospital which is the State of New Mexico's primary teaching hospital, the State of New Mexico's only Level I trauma center, and the State of New Mexico's comprehensive safety net hospital, with a special relationship to the Indian Health Services and the Native American tribes and pueblos. UNM is also the home of the State of New Mexico's only NCI-designated Comprehensive Cancer Center and the only Clinical and Translational Sciences Center. UNM's stated mission is: "[a]s the state's premier institution of higher learning and provider of health care, The University of New Mexico promotes discovery, generates intellectual and cultural contributions, honors academic values, and fosters an educated, healthy, and economically

vigorous New Mexico." Vision, .Mission, & Values :: UNM 2040: Opportunity Defined | The University of New Mexico.

5. UNM has its primary campus in Albuquerque, New Mexico, with a Health Sciences Rio Rancho campus and four (4) branch campuses which are community colleges.

Reliance on NIH Funding

6. In fiscal year 2024, UNM received funding through the National Institutes of Health ("NIH") to support 202 projects, with a total of $95,929,910.00 awarded. These included awards from:

Agency for Healthcare Research and Quality
CDC - National Center for Chronic Disease Prevention and Health Promotion
Cooperative Human Tissue Network
John E. Fogarty International Center for Advanced Study in the Health Sciences
National Center for Advancing Translational Sciences
National Center for Complementary and Integrative Health
National Cancer Institute
National Center for Research Resources
National Eye Institute
National Human Genome Research Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Biomedical Imaging and Bioengineering
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institute on Drug Abuse
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 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 Library of Medicine
Office of the Director

7. These grants have been submitted by 126 faculty and would provide support for the key personnel including hundreds of faculty, staff, and trainees.

8. The work done by UNM on NIH funded projects provides critical support for groundbreaking research, advances in medical science, improvements in public health, as well as training and education of the future workforce. Additionally, it fosters innovation in STEMM (Science, Technology, Engineering, Mathematics, and Medicine) fields, ultimately enhancing the quality of life for people worldwide.

Processes for NIH Grant Awards

9. The sponsored project/grant offices at UNM work with researchers to submit grant applications and track grant applications and awards.

10. Based on my work as Executive Vice President for Health Sciences and Chief Executive Officer of the UNM Health System, I have an understanding of the NIH grant process. based on my many years in the various roles I outlined above.

11. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

12. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles to balance portfolios and

meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

13. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether to fund the grant is made. After the advisory council meets, a Notice of Award (NOA) is issued confirming whether the grant will be funded.

14. The process for competitive renewals of existing grants is very similar and occurs every 5 years for many NIH grants. As for new projects, competitive renewals require review by a study section and subsequent consideration of the score during an advisory council meeting.

15. The budget process at UNM relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within 5 months of submission.

16. Once a grant receives a score, UNM is able to consider whether to include the funding coming from that grant as part of its budget for the coming year.

17. As of April 5, 2025, UNM has approximately 256 proposals totaling $344,328,835.00 awaiting NIH review processes. This includes a pending C06, "Biomedical Research Facilities" grant which was submitted in January 2025; this grant will support adding space onto the existing Center for Memory and Aging to accommodate the Alzheimer Disease and Research Center.

Terminations of NIH Grants

18. Since April 5, 2025, UNM has had six (6) NIH grants terminated.

19. The terminations UNM has received as of April 5, 2025 are attached my Declaration as Exhibits 1 through 6.

20. These terminations will result in the loss of $10,243,849.70 in research money to UNM. NIH has terminated five essential research training grants at UNM. These prestigious grants support vital biomedical workforce development programs that provide advanced training for our students: 1) Institutional Research and Academic Career Development Award (IRACDA) Post-Doctoral program – trains post-doctoral fellows for research and teaching careers in academia; 2) The Leading Equity and Diversity in the Medical Scientist Training Program (LEAD MSTP) – to support biomedical research training of our MD/PhD students for developing the clinical research workforce; 3) the Initiative to Maximize Student Diversity at the University of New Mexico Health Sciences (IMSD) grant – to support predoctoral trainees in the Biomedical Sciences Graduate Program; 4) the Undergraduate Research Initiative for Student Enhancement (U-RISE) – to train and prepare undergraduate students for doctoral programs and careers in biomedical research; and 5) the Post-baccalaureate Research Education Program at UNM (PREP@UNM) – to enhance the ability of individuals in the biomedical sciences to gain entry to and succeed in nationally recognized PhD programs and research careers. These training grants provide structured training and mentorship programs as well as financial support, including tuition and stipends, to advance students' education and career opportunities in biomedical research; currently, we have approximately 57 students enrolled at different stages in these programs. Some of these programs have been at UNM for over 20 years.

21. The termination notices for these grants provide very little to explain the termination, stating, for example: "I am writing to let you know that due to changes in NIH/HHS priorities, the **"grant name"** 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." The same language was received for two other training grants.

22. In addition, UNM is expecting termination of a Faculty Institutional Recruitment for Sustainable Transformation (FIRST) grant; this grant supported hiring nine research-active tenure-track faculty at UNM. NIH websites state that "A closeout of the FIRST program has taken place and awardees are no longer receiving funding." We anticipate a loss of approximately $5.1 million associated with this grant. Termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. Prior to receipt of the termination, however, UNM had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was UNM provided with any updated "agency priorities" or an alternative NOFO with which its research must align. When one of the fellows (Ph.D. students) followed up on the funding for the second year of their F31 training grant, they received the following message: "...the diversity F31 program has ended due to NIH/HHS priorities. Further awards will not be made, but you can continue to draw funds from this award until it is terminated no later than the end of the current budget period. However, awards may terminate sooner based on NIH/HHS priorities." NIH F grants, also known as NIH Individual Fellowships, are designed to provide research training opportunities to individuals at various stages of their academic and professional careers. Currently, the University has eight active F31 grants and we anticipate loss of $360,185 associated with these grants.

Admissions, Training and Workforce

23. UNM uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

24. Due to recent changes in federal policies and NIH priorities, the UNM School of Medicine anticipates reducing its incoming class of biomedical sciences PhD students by 31.6%, along with a 40% reduction to the incoming cohort of MD/PhD students. In addition, we have received significant cuts to our postdoctoral programs, including the complete loss of our 2025-2026 cohort of 4 postdoctoral scholars in our Academic Science Education and Research Training (ASERT) program that is administered by the UNM Comprehensive Cancer Center. This decision follows the termination of several key NIH-funded diversity-focused training programs that have long supported our efforts to build a strong and inclusive biomedical research workforce in the state of NM. These include the following: 1) the Initiative for Maximizing Student Development program, which funded 15 students in our Biomedical Sciences Graduate Program, and was focused on recruiting and retaining students from underrepresented backgrounds and preparing them for a range of research careers; 2) our Medical Scientist Training Program, which funded two students in our integrated MD/PhD program that emphasizes training in health equity, bioengineering, and computational sciences; and 3) our IRACDA-funded ASERT postdoctoral program, which funded 8 PhD scholars and provided interdisciplinary research and teaching training in partnership with local minority-serving institutions, namely New Mexico State University, Central New Mexico Community College, and Southwestern Indian Polytechnic Institute. These programs were terminated despite strong institutional support and long-standing records of success in developing highly successful researchers who contributed to new scientific discoveries to advance healthcare in the state of NM, and who helped bring in millions of dollars in annual research funding that significantly impacted our state economy. Their loss has created immediate disruptions to our research enterprise, limiting our ability to train and retain talented students and postdoctoral fellows. In addition, the absence of these training opportunities will have

lasting consequences on the capacity of UNM to advance scientific discovery, particularly in addressing health disparities and biomedical challenges that disproportionately affect New Mexico and the Southwest.

Michael E. Richards, M.D., MPA

Date: April 7, 2025

Exhibit 1

Erin Fitzgerald

From: Erin Fitzgerald
Sent: Thursday, March 27, 2025 3:12 PM
To: Ellen Fisher; Ariadna Vazquez; Sharon Nepstad
Cc: Teresa Hammitt
Subject: FW: Information regarding URISE award T34 GM145428-03 2UM10 004914-00001A
Attachments: NIH_NOA_5T34GM145428-03 - 2UM10_Takacs_CONT.pdf; T34_2UM10 _Abstract_Narrative.pdf; T34_2UM10_Budget_Just.pdf

Importance: High

Good Afternoon,

We received notice from NIH today on Cristina Takacs' T34 training grant entitled, "U-Rise at the University of New Mexico," to cease work outside of the current budget period (which end 3/31/25) while NIH assesses this project and it's continued funding. It was anticipated to be funded through 2027.

This project funds 10 trainees per year, a graduate student and a student program specialist. I'm including the original abstract, project narrative and budget/justification for further context. I will add to the SWO tracker shortly.

Thank you,

ERIN FITZGERALD, MBA, CRA | Associate Director, UNM Office of Sponsored Projects | 505-277-2665

From: Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov>
Sent: Thursday, March 27, 2025 12:00 PM
To: Rebecca Valdez <rvaldez3@unm.edu>
Subject: Information regarding URISE award

You don't often get email from rosenzwj@nigms.nih.gov. Learn why this is important

[EXTERNAL]

RE: T34 GM145428-03

Contact PI: TAKACS-VESBACH, CRISTINA D

Organizational Representative MRS REBECCA VALDEZ,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management

System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig
Grants Management Team Leader, GAB
National Institute of General Medical Sciences, NIH/DHHS

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Notice of Award
FAIN# T34GM145428
Federal Award Date
03/14/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF NEW MEXICO
1700 LOMAS BLVD NE STE 2200
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)
868853094

6. Recipient's Unique Entity Identifier
F6XLTRUQJEN4

7. Project Director or Principal Investigator
Cristina D. Takacs-Vesbach, PHD

cvesbach@unm.edu
505-277-3418

8. Authorized Official
Rebecca Valdez

Federal Agency Information

9. Awarding Agency Contact Information
Adam S Barnhart

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
adam.barnhart@nih.gov
(301) 451-1942

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
5T34GM145428-03

12. Unique Federal Award Identification Number (FAIN)
T34GM145428

13. Statutory Authority
42 USC 288 42 CFR 66

14. Federal Award Project Title
U-Rise at the University of New Mexico

15. Assistance Listing Number
93.859

16. Assistance Listing Program Title
Biomedical Research and Research Training

17. Award Action Type
Non-Competing Continuation

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	$336,892
20 a. Direct Cost Amount	$315,220
20 b. Indirect Cost Amount	$21,672
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$336,892
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$336,892
26. Project Period Start Date 04/01/2022 – **End Date** 03/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,006,140

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.

Notice of Award

MARC NATIONAL RESEARCH SERVICE AWARD
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

SECTION I – AWARD DATA – 5T34GM145428-03

Principal Investigator(s):
Cristina D. Takacs-Vesbach, PHD

Award e-mailed to: osp@unm.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $336,892 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEW MEXICO 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 T34GM145428. 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)

Stipends	$143,400
Tuition & Fees	$44,320
Trainee Travel	$27,500

Training related Expenses	$100,000
Federal Direct Costs	$315,220
Federal F&A Costs	$21,672
Approved Budget	$336,892
Total Amount of Federal Funds Authorized (Federal Share)	$336,892
TOTAL FEDERAL AWARD AMOUNT	$336,892
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$336,892

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$336,892	$336,892
4	$336,892	$336,892
5	$336,892	$336,892

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1856000642A1
Document Number: TGM145428A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026
GM	8472205	$336,892	$336,892	$336,892

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: T412SJ / **OC**: 41013 / **Released**: Rosenzweig, Justin 03/13/2024
Award Processed: 03/14/2024 12:17:19 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5T34GM145428-03

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 – 5T34GM145428-03

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.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) T34GM145428. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year

period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – GM SPECIFIC AWARD CONDITIONS – 5T34GM145428-03

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.

1. This grant must be administered in accordance with the guidelines and restrictions described in the Initiative for Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program announcement PAR-21-146 available at: https://grants.nih.gov/grants/guide/pa-files/PAR-21-146.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 Undergraduate Research Training Initiative for Student Enhancement (U-RISE) (T34) program as well as answers to Frequently Asked Questions, please visit: https://www.nigms.nih.gov/training/RISE

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-23-076 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-076.html)

4. SUMMER RESEARCH EXPERIENCE: This award includes $17,500 to support the Summer Research Experience (SRE) for 50% of the total trainee slots awarded. These funds are based on $3,000 per trainee slot for per diem expenses for ten weeks and $500 for travel plus 8% F&A costs. They are restricted solely for this purpose and may not be rebudgeted into other categories. Additionally, funds have been included in future years for this purpose. Travel to foreign sites (a country other than the United States and its territories) is not allowed for any trainee while appointed to the grant. Please review the SRE guidelines posted at https://www.nigms.nih.gov/training/T34/Pages/sre.aspx

5. 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.

6. This award includes funds to support ten (10) trainees (120 Trainee Months). The maximum number of trainees that may be appointed without the prior written approval of NIGMS staff is ten (10) trainees (120 Trainee Months).

7. 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.

8. In accordance with NIH Guide Notice NOT-OD-10-072, appointment documentation

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

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. Failure to submit documentation may result in an expenditure disallowance or a delay in continued funding.

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.

9. 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.

10. The next non-competing progress report for this grant is due on August 15, 2024.

11. 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

12. 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

The NIGMS WWW home page is at http://www.nigms.nih.gov

SPREADSHEET SUMMARY
AWARD NUMBER: 5T34GM145428-03

INSTITUTION: UNIVERSITY OF NEW MEXICO

EXHIBIT 2

Erin Fitzgerald

From: UNM Awards
Sent: Thursday, April 3, 2025 10:41 AM
To: Erin Fitzgerald; Teresa Hammitt
Cc: Brianne Lucero; Ernesto Trujillo; Anthony Gallegos
Subject: NIGMS Funding Update (SL Award: 005758-00001A (2VX10) Biology Department)

Importance: High

Hello Erin & Teresa,

Below is another termination that we received. This is for Dr. Kelly Miller.

I will notify the PI and department and will process this in SL ASAP.

Thanks

Rebecca Valdez

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 11:15 AM
To: UNM Office of Sponsored Projects <osp@unm.edu>
Subject: NIGMS Funding Update

You don't often get email from kenneth.gibbs@nih.gov. Learn why this is important
[EXTERNAL]

Re: GM075149-19

Dear Wester, Timothy,

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

AWD0008493 / 21-004522

FDP Subaward Amendment

Awarding Agency	National Institutes of Health (NIH)	Amendment No	3
PTE/Prime Award No.	5R01AA029088-03	Subaward No	CON-80004024(GR117911)

Pass-Through Entity (PTE)		Subrecipient
Yale University	Entity Name	The Regents of the University of New Mexico
gcat3@yale.edu	Contact Email	osp@unm.edu
John Pachankis, PhD	Principal Investigator	Katie Witkiewitz, PhD

Project Title: A unified protocol to address sexual minority women's minority stress, mental health and hazardous drinking

Cumulative Budget Period(s) (Agreement Start Date) – (End Date of Latest Budget Period)	Amount Funded This Action	Total Amount of Funds Obligated to Date
Start Date: 09/12/2022 End Date: 03/21/2025	$ 0.00	$ 55,005.00

Subrecipient Cost Share ☐ | Subject to FFATA ■ | Subrecipient UEI (Unique Entity Identifier - May leave blank if unchanged from prior Agreement)

Amendment(s) to Original Terms and Conditions

This Amendment revises the above-referenced Subaward Agreement as follows:

☐ **Additional Budget Period**

☐ **No Cost Extension**

☐ **Additional Funding**

☐ **Deobligation**

Carryover is Automatic Carryover is allowed across all budget periods.

☐ **Carryover Authorized**

■ **Detailed Budget/Scope of Work/Notice of Award Attached** (Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")

A Notice of Award is incorporated by attachment to this Amendment.

■ **Other (See Below)**

This Subaward is terminated, effective 3/21/2025.

For clarity: all amounts stated in this amendment are in United States Dollars.

All other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Date		Date	
Name	Philip Frum, MA, CRA	Name	Erin Fitzgerald
Title	Subaward Manager	Title	Associate Director, Office of Sponsored Projects, UNM

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Notice of Award
FAIN# R01AA029088
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
YALE UNIV
150 MUNSON ST
NEW HAVEN, CT 06511

2. Congressional District of Recipient
03

3. Payment System Identifier (ID)
1060646973A1

4. Employer Identification Number (EIN)
060646973

5. Data Universal Numbering System (DUNS)
043207562

6. Recipient's Unique Entity Identifier
FL6GV84CKN57

7. Project Director or Principal Investigator
John Edward Pachankis, PHD (Contact)
Professor
john.pachankis@yale.edu
2037853710

8. Authorized Official
Ms. Tina Varick

Federal Agency Information

9. Awarding Agency Contact Information
Heather P. Olusoga

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
Heather.Olusoga@nih.gov
301-443-8767

10. Program Official Contact Information
Robert Freeman
Health Scientist Administrator
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
rfreeman@mail.nih.gov
301443-8820

Federal Award Information

11. Award Number
5R01AA029088-03

12. Unique Federal Award Identification Number (FAIN)
R01AA029088

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
A unified protocol to address sexual minority women's minority stress, mental health and hazardous drinking

15. Assistance Listing Number
93.273

16. Assistance Listing Program Title
Alcohol Research Programs

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$737,885
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$737,885
26. Project Period Start Date 09/12/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,282,298

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Judy Fox

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

SECTION I – AWARD DATA – 5R01AA029088-03 REVISED

Principal Investigator(s):
TONDA L HUGHES, PHD
John Edward Pachankis (contact), PHD

Award e-mailed to: ospadmin3@yale.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 YALE 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 On Alcohol Abuse And Alcoholism of the National Institutes of Health under Award Number R01AA029088. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Judy Fox
Grants Management Officer
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$190,490
Fringe Benefits	$89,249
Personnel Costs (Subtotal)	$279,739
Consultant Services	$4,500
Travel	$3,420
Other	$72,207
Subawards/Consortium/Contractual Costs	$135,109
Federal Direct Costs	$494,975
Federal F&A Costs	$242,910
Approved Budget	$737,885
Total Amount of Federal Funds Authorized (Federal Share)	$737,885
TOTAL FEDERAL AWARD AMOUNT	$737,885
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$737,885	$737,885

Fiscal Information:

Payment System Identifier:	1060646973A1
Document Number:	RAA029088A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024
AA	8470415	$737,885

NIH Administrative Data:
PCC: AE FD / **OC**: 41025 / **Released**: 03/24/2025
Award Processed: 03/25/2025 12:08:55 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AA029088-03 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 – 5R01AA029088-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to

report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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) R01AA029088. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines. This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to 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

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: It is the policy of NIH not to prioritize gender identity. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, this project is terminated. The Yale University may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

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 award is issued in accordance with NIH FY24 Fiscal Policies (see NIH Guide Notice NOT-OD-24-109 at (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-109.html), including salary limitations as indicated below.

SALARY LIMITATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Current salary cap levels can be found at https://grants.nih.gov/grants/policy/salcap_summary.htm.

PHASE III CLINICAL TRIAL: As indicated in Section III of this Notice of Award, this award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial was amended in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, October 9, 2001 (see NOT-OD-02-001, https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in the Guidelines.

DATA AND SAFETY MONITORING: This award is subject to the current Data and Safety Monitoring Plan (DSMP) submitted and previously approved by NIAAA in accordance with the NIAAA Data and Safety Monitoring Guidelines at http://www.niaaa.nih.gov/research/guidelines-and-resources/data-and-safety-monitoring-guidelines. Any changes in the DSMP must be reviewed and approved by the NIAAA Program Official.

DISSEMINATION PLAN: The clinical trial(s) supported by this award is subject to the dissemination plan previously submitted to and approved by NIH 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 primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

Type text here

In submitting this RPPR, the AOR (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

GRADUATE STUDENTS: Per the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf), NIH may award the actual amount requested for a graduate student's salary, fringe benefits, and tuition remission up to a maximum of the National Research Service Award (NRSA) zero-level stipend in effect at time of the competing award (see http://grants.nih.gov/training/nrsa.htm).

PRIOR APPROVALS: In keeping with NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grant recipient institution must secure and retain the signatures of all PIs following their own internal processes.

INFORMATION: This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (see http://grants.nih.gov/grants/policy/policy.htm#gps).

NIAAA DATA ARCHIVE (NIAAADA) DATA SHARING REQUIREMENT: This award is subject to the data sharing guidance outlined in NOT-AA-23-002 https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-002.html.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AA029088-03 REVISED

INSTITUTION: YALE UNIVERSITY

Budget	Year 3
Salaries and Wages	$190,490
Fringe Benefits	$89,249
Personnel Costs (Subtotal)	$279,739
Consultant Services	$4,500
Travel	$3,420
Other	$72,207
Subawards/Consortium/Contractual Costs	$135,109
TOTAL FEDERAL DC	$494,975
TOTAL FEDERAL F&A	$242,910
TOTAL COST	$737,885

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	67.5%
F&A Cost Base 1	$359,866
F&A Costs 1	$242,910

EXHIBIT 4

Outlook

Fw: NIGMS Funding Update

From Stacy M Catanach <SCatanach@salud.unm.edu>
Date Sat 4/5/2025 3:32 PM
To Stacy M Catanach <SCatanach@salud.unm.edu>

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 11:16 AM
To: HSC-PreAward <HSC-PreAward@salud.unm.edu>
Subject: NIGMS Funding Update

[[-- External - this message has been sent from outside the University --]]

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.

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

Type text here EXHIBIT 5

Outlook

Fw: NIGMS Funding Update - Termination for Nancy Kanagy - FP13848

From Stacy M Catanach <SCatanach@salud.unm.edu>
Date Sat 4/5/2025 3:28 PM
To Stacy M Catanach <SCatanach@salud.unm.edu>

From: Gibbs, Kenneth (NIH/NIGMS) [E] <kenneth.gibbs@nih.gov>
Sent: Wednesday, April 2, 2025 11:16 AM
To: HSC-PreAward <HSC-PreAward@salud.unm.edu>
Subject: NIGMS Funding Update

[[-- External - this message has been sent from outside the University --]]

Re: GM144834-04

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 **Initiative for Maximizing Student Development (IMSD)** program has been terminated. Your institution can continue to draw funds on any active award for allowed costs that are within scope and consistent with the Grants Policy Statement. Further awards will not be made, and NIGMS will not permit no-cost extensions. We advise against recruiting future cohorts.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 6

Outlook

Fw: NIGMS Funding Update

From Stacy M Catanach <SCatanach@salud.unm.edu>
Date Sat 4/5/2025 3:29 PM
To Stacy M Catanach <SCatanach@salud.unm.edu>

Begin forwarded message:

From: "Gibbs, Kenneth (NIH/NIGMS) [E]" <kenneth.gibbs@nih.gov>
Date: April 2, 2025 at 12:18:48 PM CDT
To: Diane S Lidke <DLidke@salud.unm.edu>
Subject: NIGMS Funding Update

[[-- External - this message has been sent from outside the University --]]

Re: GM088021-16

Dear Dr. Lidke,

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

EXHIBIT 57

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814-BEM_____

DECLARATION OF LAUREN FORREST, Ph.D.

I, Lauren Forrest, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am an Assistant Professor of Psychology at the University of Oregon. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

Professional Background

3. I am an Assistant Professor of Psychology at the University of Oregon. I was awarded a Ph.D. in Clinical Psychology from Miami University in 2020. I thereafter served in a post-doctoral fellowship at Yale School of Medicine. From 2021 to 2024, I was an Assistant Professor at the Penn State College of Medicine in its Department of Psychiatry and Behavioral Health. I came to the University of Oregon in 2024 as an Assistant Professor and am well on my way to receiving tenure here. My research focus involves examining risk processes for

disordered eating and suicide, particularly among marginalized populations in the rural United States.

4. My lab is dedicated to determining how suicide and eating disorders can be effectively predicted, treated, and prevented. I lead this work because suicide and eating disorders are devastating. These problems affect millions of people worldwide every year, though the burdens are not felt equally across the population. Suicide and eating disorders disproportionately impact girls, women, and sexual and gender minorities. My lab conducts research to understand risk processes within at-risk groups. We hope to use this information to develop and disseminate effective interventions for these groups.

5. Suicide and eating disorders are incredibly complex, so much of my work uses advanced quantitative methods to capture and model this complexity. Although I historically conducted research on eating disorders, for the past four years I have prioritized building my program of research investigating suicide risk processes among sexual minorities living across the U.S.

6. I have one pending NIH grant application related to suicide risk in sexual and gender minority people. I had one active NIH grant related to suicide risk in sexual minority people. The grant provided me with support in excess of $600,000 over multiple years. This grant has now been terminated. This grant was an NIH K08 career development award. This award was the culmination of over 10 years of clinical and research training and experience. This award gave me protected time to complete intensive and specialized research training, which would prepare me to transition into a fully independent and federally funded investigator. I also have a pending, highly rated application for a larger “R01” grant pending with NIH that is

unlikely to move forward in the funding "pipeline," given its focus on sexual and gender minority people.

7. My K08 grant focused on suicide, which is an urgent public health problem. More than 13 million Americans think about suicide every year, more than 1.5 million attempt suicide every year, and nearly 50,000 die by suicide every year. My grant's overarching aim was to understand what causes people to think about and attempt suicide. Developing a comprehensive understanding of what things lead to suicide risk helps researchers and clinicians understand how to more effectively prevent suicide. The grant was specifically studying suicide risk among sexual minority Americans (i.e., people whose sexual orientation is lesbian, gay, or bisexual) who live in rural areas of the United States. I focused on this specific subgroup of the population for three reasons. (1) Sexual minority people experience suicidal thoughts and behaviors 3–6 times more frequently than heterosexual people, and suicide is the leading cause of death among sexual minority adults. (2) Despite having high prevalence of suicidal thoughts and behaviors, sexual minority people are almost never included in suicide research. (3) Rural location is a social context that could uniquely impact suicide risk for sexual minority people. Suicide research rarely incorporates contextual variables. Understanding how context contributes to suicide risk has implications for how we can more comprehensively study—and prevent—suicide among many different groups of people, including but not limited to sexual minority people.

8. This K08 grant was abruptly terminated on 3/21/25. The NIH states that the grant was terminated because it no longer aligns with agency priorities. The abrupt termination of this grant is, without exaggeration, the biggest professional setback an early-career investigator can

face. This termination effectively ends my ability to produce research that could contribute to saving lives. Specific details are provided below.

9. Furthermore, the delay in grant review, renewals, and terminations severely impacts me and my lab and impairs important discoveries intended to reduce a leading cause of death among the populations I am studying. As of today, my most important and potentially impactful grant has been canceled and I have no real hope for future funding given the ideologically driven shutdown of the processes for awarding future research funding.

10. **Canceling this grant is the abandonment of a program of research that addresses a life and death problem in a population that almost no one is studying.** I developed my program of research on suicide risk among sexual minorities because I realized that virtually no one was studying how or why sexual minority adults think about suicide or attempt suicide at an acute, clinically actionable timescale (over hours or days). Statistics show clearly why this is an important problem to be studying. Sexual minority people have 3–6 times higher prevalence of suicidal thoughts and behaviors compared to heterosexual people. *Suicide is the leading cause of death for sexual minority people.* And yet, sexual minority people are almost never included in studies assessing acute suicide risk. This is clearly an important gap, and I designed my K award's research and training aims to provide me with experiences that would make me uniquely prepared to fill this specific gap.

11. I spent the last four years building my research program focused on acute suicide risk in sexual minority adults. I was on track for this research program to be highly successful but this cancelation and the ideological restriction of further research funding puts my entire research program at risk. This grant was funded after a competitive process that involved review by experienced scientists to test its proposed methodology and potential to advance important

understandings in behavioral health. The cancellation and the subsequent indication that similar research will not be funded due to ideological positions is an existential challenge to scientific research with established promise to save lives.

12. To document that my research program was on track to be highly successful, my "K" award was funded on its first submission, and my first R01 application (which I have counted on to accelerate my research in this field) was scored on its first submission (which is an achievement, given that only the top 50% of grants are scored at each study section meeting). I resubmitted the R01 in March 2025. However, due to the current administration's abrupt shift away from funding health disparity research—including studies on sexual minorities, and despite the fact that suicide is the leading cause of death among sexual minorities—it is now unlikely that this R01 or any future grant on suicide in sexual minorities will be funded. Since large-scale research depends on federal grants, I can no longer continue this vital work, despite its urgency and potential to save lives.

13. In addition to critical support for the specific suicide-related research, the cancelled K grant provided $25,000 per year (for 4 years) for research and training to support my development as an independent investigator. I planned to use the funds to complete advanced courses in research, data analysis, and mixed methods. Without the award, I lack the resources for this training. I also now lack the resources to complete the research study I proposed. Without these experiences, my ability to pursue future suicide research is now severely limited.

14. My grant was propelling scientific discovery of what leads people to think about and attempt suicide. Although the grant focused on sexual minority people, the data collected under the grant would have produced scientific discoveries relevant to all people, regardless of their sexual orientation. **These scientific discoveries are now cumulatively delayed.** Without

the award, I will employ fewer research personnel for a shorter duration. This will delay collecting the necessary and critical preliminary data for future grants. I anticipate that collecting this preliminary data will now take me approximately 10 years. In the next 10 years, roughly half a million Americans will die by suicide. This terminated grant's findings and scientific discoveries could have prevented some of these deaths.

15. Employing fewer staff for shorter durations compounds delays in my lab's scientific discoveries, because a key task for an early-career investigator is to build a team who will help them carry out the lab's scholarship. A lab's first research personnel are critical for a lab's efficiency. The investigator thoroughly trains their first research staff, and over months and years the investigator and staff work in tandem to develop rigorous lab protocols and standard operating procedures. When it is time to expand research personnel, such as after securing a new grant, the existing and thoroughly trained staff play a primary role in searching for, hiring, training, and mentoring new staff. Although the investigator supervises the training and mentorship of new staff, the investigator spends significantly less time on these activities than they do when they are hiring initial staff. This means that the investigator now has more time to be analyzing data, publishing and disseminating findings.

16. The award and my pending grant would have allowed continuity in my research personnel. This continuity is now impossible for me to achieve. I currently have funds to support salary for one research staff member for one year. The award would have allowed me to support this staff's salary for at least two more years. Once I expend my current funds, I will have no research staff until I secure a new grant. This may take up to 10 years, given that I must abandon my current program of research, which is no longer fundable due to the administration imposing their ideological positions on science. Once I secure a new grant, I will have to build my team

from the ground up again, taking significant time to hire and train personnel. The more time I spend hiring and training, the less time I have for conducting my scholarship. The termination of the award thwarts my ability to build my team and maintain my lab's foundation, which will have compounding effects for my lab's scientific discoveries. Having the grant helped propel my lab's science and team development.

17. I had plans to hire one part-time research staff member to begin in Summer 2025. With the grant's termination, I can now no longer hire for this position. Importantly, this type of research position is often given to individuals who want to pursue a PhD in clinical psychology but who need more research experience to be competitive for this type of graduate program. Thus, not hiring research staff means fewer students will obtain the necessary full-time research experience they need to be competitive for admission to clinical psychology PhD programs.

18. Without me conducting large-scale federally funded research, I will attract and train fewer clinical psychology PhD students because I will have less data to train them on and no lab-provided funds to pay their stipends. This will lead to fewer researchers and licensed psychologists entering the workforce—an especially serious issue given the current mental health crisis in the U.S., where demand for psychological care far exceeds the supply of qualified providers.

19. Society has now lost the benefit of the science that my lab and staff would have conducted.

Reliance on NIH Funding

20. In fiscal year 2024, my lab received funding through NIH to support one project, totaling $155,264. I received these funds under one grant, which would have run from September 2024 to July 2028.

21. Although this is a small amount relative to more senior investigators, this amount of funding for a new assistant professor is remarkable.

22. There are no alternative funding sources to replace my terminated grant or the level of funding future NIH grants would have provided.

23. My lab will employ its first worker beginning in June 2025. This worker would be funded partially through my NIH grant. I will be required to terminate this staff's employment after one year if the K award is not reinstated. As described above, the terminated award provided necessary and critical preliminary data for my future grants. Without the terminated award, I will be unable to secure new grants. No new grants means no funding to maintain staff. I also have PhD students who work in my lab who are relying on the lab's NIH-funded work to complete their own research and earn their degrees. Their training will be substantially impacted without NIH funding.

24. Through the peer review process, grant applications are given a score and sometimes assigned a percentile as well. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded. What constitutes a fundable score is dependent on several factors as every institute or center, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. I would consider a percentile less than 10% as highly likely to receive funding.

25. In my experience, termination of an active grant is also extremely rare and I have never had a grant terminated. To my knowledge, they have only occurred in cases of serious scientific or budgetary misconduct, and typically with prior notice and multiple opportunities to respond and correct any underlying issues.

Irregularities in Grant Terminations

26. As noted above, in late March, I received a communication from NIH purporting to terminate the grant because it does not "effectuate agency priorities." It went on to state "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." Beyond this assertion, the letter did not include any explanation on what those new agency priorities are, or why my project specifically no longer furthers those priorities. The implication that my study is one that "ignores biological realities" is scientifically baseless. It is an indisputable fact that my study was funded only after a vigorous review by seasoned scientists and was, of necessity, based on a rigorous review of prior scientific discoveries. There is no serious question that sexual minorities constitute at least 10% of the United States' population and unchallenged scientific research published in the most prestigious scientific journals, has, for decades, established the fact that members of this population are at vastly greater risk of suicide attempts and death by suicide.[1]

[1] See., e.g., Chum, A., Kim, C., Nielsen, A., Dusing, G. J., O'Campo, P., Matheson, F. I., Barker, L., Vigod, S., Ling, V., Fung, K., & Kennedy, S. (2023). Disparities in suicide-related behaviors across sexual orientations by gender: A retrospective cohort study using linked health administrative data. *American Journal of Psychiatry, 180,* 660–667. doi: 10.1176/appi.ajp.20220763; Lynch, K. E., Gatsby, E., Viernes, B., Schliep, K. C., Whitcomb, B. W., Alba, P. R., DuVall, S. L., Blosnich, J. R. (2020). Evaluation of suicide mortality among sexual minority US Veterans from 2000 to 2017. *JAMA Network Open, 3:* e2031357. doi: jamanetworkopen.2020.31357; Salway Hottes, T., Bogaert, L., Rhodes, A. E., Brennan, D. J., & Gesink, D. (2016). Lifetime prevalence of suicide attempts among sexual minority adults by study sampling strategies: A systematic review and meta-analysis. *American Journal of Public Health, 106,* e1–e12. doi: 10.2105/AJPH.2016.303088.

27. It should also be noted that my grant was not a research study based on gender identity. My grant focused on sexual orientation (which is distinct from gender identity), and specifically included participants whose sexual orientation was lesbian, gay, or bisexual (i.e., sexual minorities). Thus, the stated reason or the termination is not applicable to my grant.

28. From the context, and by comparison to grants of other psychologists I work with that were not cancelled, I am informed and believe that the reason NIH has cancelled my K08 grant is because it includes a focus on sexual minorities. I am deeply troubled that this determination is based solely on ideology.

29. It is unfathomable that the Agency would explicitly reject and no longer consider suicide research with sexual minorities to be among Agency priorities. Suicidal thoughts and behaviors are highly prevalent in sexual minorities, and much higher than in heterosexuals. Scientific evidence is incredibly clear about this. Sexual minorities' increased suicide risk is very real and very devastating. I cannot conceive of a logical scientific reason why research studying suicide in a population known to have very high prevalence of suicide would be rejected and not among agency priorities. I was not referred to any new policy statement or regulation that described the new agency priorities.

30. My understanding is that NIH's purpose is to conduct and support biomedical and behavioral research for the entire population, research training, and the dissemination of health information. My project advances those goals by advancing our scientific understanding of life-threatening risks in a vulnerable population.

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

31. Due to the delays and funding uncertainty, I have been forced to suspend hiring and reduce research staff hours, which risks the loss of key lab personnel who may be forced to seek other employment due to these cuts.

32. Students working in my lab who are relying on research conducted there to obtain their PhDs are likely to see years of delay in their progression and career development.

33. There is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

34. The breakdown in NIH processes is affecting my lab, my staff, my research, my career, and those individuals who stand to benefit from my research. The termination of my grant and citing reasons that are not applicable to the grant, with no explanation or remedy, is undermining my confidence in the system and making it harder to secure talent needed to continue effective research efforts. These harms are ongoing and, in many instances, irreparable.



Lauren Forrest, PhD

Date: 4/12/2025

EXHIBIT 58

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF RICHARD TANKERSLY

I, Richard Tankersley, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Graduate Studies of Portland State University. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with Portland State University staff, or from documents that have been provided to and reviewed by me.

2. I submit this Declaration in support of the States' Motion for Temporary Restraining Order.

Professional Background

3. I am the Vice President for Research and Graduate Studies at Portland State University. I joined Portland State University in August 2023 and currently serves as the Vice President for Research and Graduate Studies. Prior to this role, I was the Vice Chancellor for Research and Economic Development at UNC Charlotte, where I focused on expanding research capacity. For more than 30 years, I have held faculty and research positions at institutions such as

Gonzaga University, the University of Maryland Baltimore County and the Florida Institute of Technology. I hold a Ph.D. in biology from Wake Forest University.

4. Portland State University's statutory mission is to provide students with access to a top-tier education as a key driver of economic and social mobility, a source of growth for the diverse communities in the region and a catalyst for social progress, to provide research that generates knowledge value essential for Oregon's economic growth, and to engage the professional expertise of its faculty to solve social problems.

5. Portland State University has a single campus with approximately 15,885 undergraduates and 4,585 graduate students enrolled in Fall 2024. In Fall 2024, Portland State University employed approximately 5,212 employees including research and instructional faculty, academic professionals and managers, administrators, classified staff and student employees.

6. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

7. The NIH meeting blockade severely impacts Portland State University by creating uncertainty in the future of all of our current awards and pending proposals, leading to a decrease in talented graduate student acceptances, the loss of current talented staff due to delays in

funding decisions for new awards and/or renewals, and a decrease in funding for programs which train future STEM scientists and directly contribute high quality employees to the workforce.

Reliance on NIH Funding

8. Portland State University received funding through the National Institutes of Health ("NIH") to support thirty-five (35) active projects, with $4,677,130 incrementally funded directly to us as primary recipient for fiscal year 2024, of $42,573,132 in overall obligated funds. Twenty-one (21) of the awards were funded directly to PSU from NIH, fourteen (14) were funded through subaward agreements from other institutions.

9. Portland State University receives NIH grants across a variety of institutes encompassed within the NIH, including NCCIH, NIAID, NIDA, NIDCD, NIEHS, NIGMS, and NIMH.

10. Through those NIH grants, over the past year Portland State University funded fifty-five (55) researchers, including twenty-one (21) Graduate Research Assistants and undergraduate students.

11. The work done by Portland State University on NIH funded projects provides research, education and training in Biomedical Sciences, Speech & Hearing Sciences, Biology, Public Health and Health Sciences, Mathematics, Chemistry, Psychology, Social Sciences, and other programs.

12. Portland State University provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Oregon economy.

Typical Timeline and Processes for NIH Grant Awards

13. The Sponsored Projects and Administration Office at Portland State University works with researchers to submit grant applications and tracks grant applications and awards.

14. Based on my work as Vice President for Research and Graduate Studies at Portland State University and my work as Vice Chancellor for Research and Economic Development at UNC Charlotte, I have an understanding of the NIH grant process.

15. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

16. What constitutes a fundable score is dependent on several factors as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding.

17. After the study section, the grant application is sent to an "advisory council" where the ultimate decision on whether or not to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

18. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

19. The budget process at Portland State University relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within nine (9) months of submission.

20. Once a grant receives a score, Portland State University is able to plan on whether to include the funding coming from that grant as part of its budget for the coming year.

Delays and Irregularities in the Processing of NIH Grant Applications

21. Since late January 2025, Portland State University has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils be canceled or otherwise not scheduled, and grant application scoring has been significantly delayed.

22. Portland State University has not received formal notice of changes for many of these grants.

23. As of April 10th, 2025, Portland State University has approximately two proposals totaling $3,440,899 awaiting NIH study section review.

24. As of April 10th, 2025, Portland State University has three proposals totaling $2,252,492 that received possibly fundable scores, awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

25. Since January 20th, 2025, Portland State University has had two NIH grants terminated.

26. The terminations received as of April 10th, 2025 are attached hereto as Exhibits A and B.

27. These terminations will result in the loss of $1,427,853 in research money to Portland State University.

28. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities" or "due to changes in NIH/HHS priorities, the [ ] program has been terminated." In my approximate 5 years, and 8 months time serving in leadership roles at both Portland State University and UNC Charlotte, I have not seen this language previously used to cancel grants.

29. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, Portland State University had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was Portland State University provided with any updated "agency priorities" with which its research must align.

30. As of April 10th, 2025, the two terminated grants both fund undergraduate training programs. U-RISE (Exhibit A) provides five cohorts of students two years of intensive research training that includes mentorship, professional development workshops and financial support to prepare historically underserved undergraduates in biomedical research careers to enter PhD programs in biomedical disciplines. To date, 15 students in Cohorts 1 and 2 have completed the program and 8 students in Cohort 3 are set to complete in spring term, now supported by bridge funding from Portland State University's limited reserves. Another 16 students in Cohorts 4-5 were anticipated to have completed the program if it had not been terminated early. The early termination will result in the loss of a second year of research for 8

students in Cohort 4, and the complete loss of training to 8 students in Cohort 5. A second program, Bridges to Baccalaureate (Exhibit B), provided research training and academic support to enable community college students interested in biomedical research careers to transfer to Portland State University to complete their Bachelor's of Science or Bachelor of Arts degrees. Due to the early termination of this grant Portland State University has been forced to use limited reserves to support 8 students through summer and has rescinded offers to 8 trainees planning to transfer in Fall 2025 who had expected to participate in research placement, receive tuition remission and be paid monthly stipends to perform research.

Comparisons Across Administrations

31. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

32. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

33. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

34. These delays and terminations are forcing Portland State University to lose talented research staff. For example, Portland State University lost one researcher whose continued employment was dependent on a timely award decision because Portland State University is unable to implement bridge funding due to a lack of discretionary reserves. Our grants that were terminated early will result in several staff having to be moved to other projects short term, but we do not have long-term funding to support their positions after June 2025.

35. Early terminations of active awards during the academic year have forced us to use limited discretionary reserves to help undergraduate students finish out their term. We will not have funds available to run these valuable programs in the future.

Admissions, Training and Workforce Disruptions

36. Portland State University uses the information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

37. Portland State University is seeing a reduction in some STEM program graduate applicants, and faculty are soliciting fewer new students due to uncertainty over incoming grant funding because of the delays in reviewing and awarding grants by NIH.

38. Portland State University is being forced to reduce the number of undergraduate STEM students we provide support for. We have been forced to rescind scholarships and stipends to 16 new undergraduate students (8 U-RISE and 8 Bridges to Baccalaureate) who had been accepted and an additional 8 (U-RISE) will be unable to complete their final year of the program due to a loss of funding.

39. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of Portland State University, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

40. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

41. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

42. Our research administration staff have received informal feedback from NIH indicating that proposals that focus on certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

43. The delays have disrupted ongoing research, as well as setting back Portland State University for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel.

44. For tenure-track faculty, NIH funding is often central to tenure and promotion criteria. Delays and cancellations are disrupting research timelines and publication pipelines, putting these faculty at risk of not meeting tenure benchmarks through no fault of their own.

45. Ongoing disruptions may cause Portland State University to miss critical deadlines for progress reports, budget justifications, or final deliverables, which could in turn make faculty or the institution ineligible for future NIH or related funding opportunities, compounding the long-term harm.

46. Uncertainty around future funding impacts our ability to project existing employee retention and student research assistant retention or recruitment efforts. Additionally, it limits our ability to accurately project indirect (Facilities and Administrative) cost returns for our research administration operations, forcing us to consider future layoffs.

47. Delays have also disrupted community services, student opportunities, and public programs.

48. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

49. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

50. These disruptions undermine the very mission of Portland State University as a public research institution committed to advancing knowledge, supporting community well-being, and promoting social mobility through research-driven education. They also erode public trust in federally funded research systems.

51. The harm from these actions is not merely immediate. Each delay or cancellation sets off a cascading effect, stalling future proposals, discouraging promising students and faculty from pursuing NIH-funded careers, and dissuading collaborators from partnering with us in the future.

Signed by:
Richard Tankersley
6894C5496E724C1...

Richard Tankersly, PhD
Vice President for Research and Graduate Studies,
Portland State University

Date: April 11, 2025

EXHIBIT A

Docusign Envelope ID: 9686B8E6-C5E1-4F39-851D-35EA04643B06

Portland State UNIVERSITY

Kathleen Choi <kchoi@pdx.edu>

Information regarding URISE award

Rosenzweig, Justin (NIH/NIGMS) [E] <rosenzwj@nigms.nih.gov> Thu, Mar 27, 2025 at 11:00 AM
To: "kchoi@pdx.edu" <kchoi@pdx.edu>

RE: T34 GM141989-04

Contact PI: KELLER, THOMAS E

Organizational Representative KATHLEEN CHOI,

NIH is currently undergoing a process to assess whether pending awards perpetuate current agency priorities. You are advised to cease project activities as of the current budget period end date of 3/31/2025. Further, please reconcile expenditures with disbursements in the Payment Management System as soon as possible but no later than 4/4/2025, for project activities that occurred through 3/31/2025. Additionally, please amend all active appointments in xTrain to end as of 3/31/2025.

Sincerely,

Justin Rosenzweig

Grants Management Team Leader, GAB

National Institute of General Medical Sciences, NIH/DHHS

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

Kathleen Choi
Portland State University
kchoi@pdx.edu

Dea Kathleen Choi:

Funding for Project Number **5T34GM141989-04** is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). 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 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.

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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]

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]

[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).

EXHIBIT B

Portland State UNIVERSITY

Jennifer Ward <jenward@pdx.edu>

Fwd: NIGMS Funding Update

Thomas Keller <kellert@pdx.edu> Wed, Apr 2, 2025 at 12:49 PM
To: Annie Lindgren <al3@pdx.edu>, Dawn Boatman <dboatman@pdx.edu>
Cc: Rick Tankersley <rtankers@pdx.edu>, Jennifer Ward <jenward@pdx.edu>, Kathleen Choi <kchoi@pdx.edu>, Kay Logan <kay.logan@pdx.edu>

Hi Annie & Dawn,

We've just received notice regarding the B2B program. It looks like we can continue through the end of the current grant year (July 31).

Please let me know if you would like to meet to discuss this latest development.

Thank you,
Tom

---------- Forwarded message ---------
From: **Gibbs, Kenneth (NIH/NIGMS) [E]** <kenneth.gibbs@nih.gov>
Date: Wed, Apr 2, 2025 at 10:13 AM
Subject: NIGMS Funding Update
To: kellert@pdx.edu <kellert@pdx.edu>

Re: GM147664-03

Dear Dr. Keller,

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.

NIGMS grants management will follow up if there is any specific information or action needed regarding your award. For additional information regarding funding opportunities that NIGMS supports, see NIGMS TWD Webpage: https://www.nigms.nih.gov/training/Pages/TWDPrograms.

If you have specific follow up questions, please email nigmstrainingmail@nigms.nih.gov and include your grant number.

Kenneth D. Gibbs, Jr., PhD, MPH
Director, Division of Training and Workforce Development
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 59

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814-BEM

Declaration of Vice President Anshuman Razdan, Ph.D.

I, Anshuman Razdan, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Innovation of The University of Oregon. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

Professional Background

2. I am the Vice President for Research and Innovation at the University of Oregon ("UO") in Eugene, Oregon. I have held that position since July 1, 2022, and I also hold a tenured full professor position in the Department of Computer Information Science at UO. Previously, I was the Associate Vice President for Research at the University of Delaware (2016 – 2022) and held faculty and administrative positions at Arizona State University (1996 – 2016).

3. UO's statutory mission is to strive for excellence in education, research, clinical practice, scholarship and community service while maintaining compassion, personal, and institutional integrity and leadership in carrying out its missions.

4. The University of Oregon has two campuses, one in Eugene and one in Portland, with over 24,000 enrolled students, which employs roughly 1,000 people on federal research projects. UO has over 200 employees that support the research enterprise. I am providing this declaration to explain the impacts of NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby grant proposals due for funding have remained unfunded indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

5. The NIH meeting blockade severely impacts the University of Oregon by delaying and terminating funding that is vital to the University's mission, particularly the focus on excellence in education and research. Due to the blockade, we are having to pause research hires and faculty are waitlisting graduate students, depriving those students of exposure and training in research.

Reliance on NIH Funding

6. In fiscal year 2024, the University of Oregon expended $54 million of funding through the National Institutes of Health ("NIH") to support over 250 projects.

7. The University of Oregon receives NIH grants across a variety of institutes encompassed within the NIH, including, National Human Genome Research Institute (NHGRI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Child Health and Human Development (NICHD), National Institute of General Medical Sciences (NIGMS), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH), National Cancer Institute (NCI), National Institute on Aging (NIA), National Institute on Drug Abuse (NIDA), National Institute on Deafness and Other Communication Disorders (NIDCD), National Institute of Neurological Disorders and Stroke (NINDS), National Center for Advancing Translational Sciences (NCATS), National Institute of Biomedical Imaging and Bioengineering (NIBIB), and National Eye Institute (NEI).

8. Through those NIH grants, UO funds approximately 150 researchers and supports approximately 100 graduate students.

9. The work done by the University of Oregon on NIH funded projects provides education and training in fundamental life sciences, biomedical research, behavioral health and biomedical engineering. NIH-funded investigators at the University of Oregon have a demonstrated track record of high impact publication and dissemination of discoveries enabled by active NIH grants, as well as significant community partnerships with schools, mental and community health agencies, and medical schools. The University of Oregon provides considerable employment benefits in the Science, Technology, Engineering and Mathematics ("STEM") workforce to the Oregon economy, both through direct employment of researchers, but also contributions to new small business growth and associated jobs through spinout companies emerging from innovations at the University.

Typical Timeline and Processes for NIH Grant Awards

10. The Sponsored Projects Services office at the University of Oregon works with researchers to submit grant applications and tracks grant applications and awards.

11. Based on my work as Vice President for Research and Innovation, I have an understanding of the NIH grant process based on my three years in the role. Further, I have been a researcher and held other research-focused administrative positions which provides me with almost 30 years of experience with NIH processes.

12. NIH grant applications are typically submitted via NIH's online portal, often in response to a Notice of Funding Opportunity ("NOFO"). From there, they are assigned to a "study section" where the grant application is subjected to peer review and judged on its scientific merit. The grant application is then given a score. If the grant receives what is called a "fundable score," there is a high probability that the grant will be funded.

13. What constitutes a fundable score is dependent on several factors, as every institute, sometimes referred to as an "IC," is different. Some publish paylines, meaning the percentiles of grants they will fund, and some do not. Paylines range from 8-20%. Most of the standing study sections result in an impact score and percentile for each proposal, but many others (special emphasis and non-CSR) will only result in an impact score, but not percentile. Program officers have latitude to recommend proposals with higher scores/percentiles in order to balance portfolios and meet specific directives. Generally, researchers would consider a percentile less than 10% as guaranteed to receive funding. In addition, competitive proposals submitted by Early-Stage Investigators are prioritized, so may be considered for funding even if outside the typical payline or impact score given the NIH's desire to support early career scholars. After the study section, the grant application is sent to an "advisory council" where the

ultimate decision on whether to fund the grant is made. After the advisory council meets, a Notice of Award is issued confirming whether or not the grant will be funded.

14. The process for competitive renewals is very similar, but it is even more consistent for a grant that has been funded in the past to be renewed.

15. The budget process at University of Oregon relies upon the NIH grant application, review, and approval cycle. Historically, we have relied on grants being reviewed and scored within nine months of submission.

16. Once a grant receives a score, faculty at University of Oregon are able to consider whether the grant will likely be able to fund the students and staff in their lab. Additionally, the University of Oregon will use the negotiated reimbursement for "indirect costs" associated with the likely award as part of the budget to support the research infrastructure.

Delays and Irregularities in the Processing of NIH Grant Applications

17. Since late January 2025, the University of Oregon has seen an unusual number of delays in the processing of NIH grant applications. Researchers have had their grant application study sections and advisory councils canceled or otherwise not scheduled, and grant application scoring has been significantly delayed. Advisory councils were cancelled and have not been rescheduled until late April, May, and June. The University of Oregon has not received formal notice of changes for the majority of these grants. For others, UO has gotten only a notification that proposals are "paused" or "under review."

18. As of April 10, 2025, the University of Oregon has 12 proposals totaling $36,562,025 that received fundable scores, awaiting NIH advisory council and Notice of Award.

Terminations of NIH Grants

19. As of April 11, 2025, the University of Oregon has had six NIH grants terminated.

20. These terminations will result in the loss of approximately $2.7 million in research money to UO.

21. The termination notices for these grants have provided very little to explain the termination, instead noting that the research no longer "effectuates agency priorities." In my almost ten years working at UO and University of Delaware, I have not seen this language previously used to cancel grants.

22. The termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. However, prior to receipt of the termination, the University of Oregon had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was the University of Oregon provided with any updated "agency priorities" with which its research must align.

23. As of April 11th, we have received 8 termination notices, of which 6 are still in effect: A) Two termination notices were received for graduate fellowships funded via the Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research. These fellowships are designed to provide funding for research education and mentorship and facilitate the success of future NIH independent researchers. The project titles for these grants are "The Development of Novel Anion Receptors for Reactive Sulfur, Oxygen, and Nitrogen Species" and "Fibroblast-lineage cell state transitions during zebrafish fin regeneration." No other active F31 NRSA awards at UO received termination notices. B) A termination notice was received for the UO PREP Program, funded via the Postbaccalaureate Research Education Program (R25) mechanism. The intent of this program is to empower postbaccalaureate students to achieve their academic and professional goals by using a multifaceted, mentored educational framework that allows students

to build and develop core competencies in experimental knowledge and inquiry, professional skills, and scientific identity. C) A termination notice was received for an award made via the Mentored Clinical Scientist Research Career Development Award mechanism (K08). The project, "Predicting acute and dynamic suicide risk in rural sexual minorities," aims to reduce current significant disparities in suicidal thoughts and behaviors among rural sexual minorities, who experience a disproportionate burden of suicidal thoughts and behaviors, often reside in high-stigma environments, and have limited access to healthcare resources. D) A termination notice was received for a subaward at the UO for an R01 NIH grant to the Center for Innovative Public Health Research for, "Transcendent Health - Adapting an LGB+ inclusive teen pregnancy prevention program for transgender boys." This study is designed to develop a text message program to prevent pregnancy in adolescent transgender boys and other gender diverse youth assigned female at birth across the United States. E) a termination notice was received for a diversity supplement on a R01, titled "Computational roles of inhibition in human action control." This supplement provided support for a graduate student to work on the project which characterizes physiological and neurochemical contributions to the neural computations underlying human motor behavior and understands how disease-related disruption of these mechanisms contributes to motor impairments.

Comparisons Across Administrations

24. In prior years, under both Democratic and Republican administrations, our institution never experienced this volume of unexplained delays or procedural breakdowns.

25. Renewals were routine and predictable. This year, even long-standing, high-performing programs are in limbo.

26. Terminations were exceedingly rare and followed due process. The current approach is without precedent in our experience.

Impact on Institutional Operations

27. UO does not have an available endowment or other sources of funds to provide significant bridge funding for the researchers impacted by funding delays and terminations. This will result in smaller research labs of associate faculty and prevent career development and growth of young faculty. Any bridge funding support that UO is able to provide to researchers will prevent the use of these funds for any other purpose, including other planned improvements to our programs and research.

28. We have paused start-up funding for new hires whose research programs depend on timely NIH awards. This includes several new hires we had provided offer letters to and for whom the University of Oregon had taken steps to prepare for their arrival.

Effect on Public-Facing or State-Supported Programs

29. Our institution operates multiple programs funded by NIH that directly partner with and/or generate data that is directly used by K-12 schools, community health agencies, mental health clinics, and other public-facing initiatives, primarily in the state of Oregon (although faculty have partners across the country). For example, one pending P50 grant (that was submitted in May 2024, reviewed with a fundable score, and should have been considered for funding at a council in January 2025) seeks to increase scientific understanding, public awareness, and delivery of effective school-based interventions that prevent and reduce mental health distress during early adolescence.

Admissions, Training and Workforce Disruptions

30. UO uses information regarding NIH grant applications and award rates to inform its admissions process, particularly at the graduate student level.

31. This 2025 admission year, UO's Division of Graduate Studies has rescinded 55 not-yet-accepted offers of admission and funding to doctoral applicants in chemistry and biology; the University would primarily use NIH money to fund these students. This number is expected to rise as the current administration cuts more federal funding. Despite a 17.5% increase in submitted graduate program applications (master's and doctoral), the number of doctoral admissions offers at UO has decreased by approximately 50%.

32. NIH training grants, including T32 and F31 mechanisms, have been affected by review and award delays. These training grants are designed to provide resources to institutions so they can train individuals in certain shortage areas (T32 grants), as well as support through predoctoral dissertation research (F31 grants). The University of Oregon currently has two T32 proposals that, under typical timelines prior to January 2025, should have progressed to study section or advisory council. These awards fund several graduate positions. Thus, the delay in funding or award impacts the number of graduate positions participating departments can feasibly recruit for.

33. This instability is affecting the recruitment and retention of quality research trainees. The inability to retain quality research trainees will have continuing effects on the research capabilities of the University of Oregon, including by limiting the individuals qualified to conduct certain research.

Concerns About FY25 Funds Being Obligated

34. We are increasingly concerned that NIH will not be able to process and obligate FY25 funds by the end of the fiscal year in September.

35. Several major proposals from our institution remain stuck at preliminary review stages, with no indication that the required advisory reviews or notices of award will occur in time.

36. Our research administration staff have received informal feedback from NIH indicating that certain topic areas are being slowed due to "heightened scrutiny" or "internal concerns."

Irreparable Harm

37. The delays have disrupted ongoing research, as well as setting back the University of Oregon for research going forward. Funding gaps have forced researchers to abandon studies, miss deadlines, or lose key personnel, including graduate students.

38. Some of these studies involve the use of animal test subjects, all of which would need to be terminated due to loss of funding and would require destruction of colonies of animals, an expense which will have to be borne by UO, and loss of research done so far. When the projects finally get funded, they will have to start from scratch.

39. Delays have also disrupted community services, student opportunities, and public programs. We have had at least five researchers report they have waitlisted or not hired graduate students because they haven't received the funding they expected by now. They cite concerns about training graduate students and post-docs, and one post-doc reported to UO that she will pursue a career outside of research.

40. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

41. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



Anshuman Razdan, Ph.D.

Date: April 13, 2025

EXHIBIT 60

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

SUPPLEMENTAL DECLARATION OF BETHANY D. JENKINS

I, Bethany D. Jenkins, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Economic Development and Professor of Cell and Molecular Biology at the University of Rhode Island. I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.

2. I submit this Supplemental Declaration in support of the States' Motion for a preliminary injunction.

Professional Background

3. I am the Vice President for Research and Economic Development and Professor of Cell and Molecular Biology at University of Rhode Island. As the Vice President for Research and Economic Development I help our community receive competitive federal awards that augment significant investments made by the State of Rhode Island in URI as our State's flagship land and sea grant university.

4. University of Rhode Island's mission is one as a student-centered research institution, that actively partners with other organizations globally and locally to advance knowledge and to develop

informed residents and leaders. URI is committed to high-quality education, community engagement, and solving the world's most important challenges. Situated on the traditional land and territories of the Narragansett Nation and the Niantic People, URI strives to create a diverse and inclusive environment for researchers, teachers, learners, and community members.

5. University of Rhode Island has three campuses throughout the state of Rhode Island, that serve approximately 14,000 undergraduate students and approximately 3,000 graduate students.

6. I am providing this supplemental declaration to document the impacts of NIH grant delays on the University of Rhode Island.

Delays of NIH Grants

7. NIH has delayed the release of already approved funds to URI.

8. URI has sought guidance and information from the NIH as to when the funds will be released. As of the date of this declaration, URI has not received this guidance.

9. NIH has not yet released the funding for a grant "Interplay of affect and physiology in the real-time prediction of return to use during community reintegration of substance users (5R01DA058636-02). Funding was expected 2/28/2025. The project aims to prevent return to substance use as it follows community reintegration following residential substance use disorder treatment, which is a critically vulnerable time that is characterized by high rates of return to use. The research uses cutting-edge technologies to identify time-sensitive proximal predictors of return to use during community reintegration. When NIH was contacted with regards to when the University can expect funding, we received the message from the agency "[w]e are waiting for guidance." In addition to the salary support to the early career investigator, delays in funding to this award impact continued work with human subjects as they receive payments for their time. These delays mean that URI cannot issue payments to our sub-awarded institutions: Brown University, University of Connecticut Health Center, Rutgers University and The Providence Center (Lifespan). Delayed funding also impacts URI's ability to pay key research personnel including graduate students and undergraduates.

10. The delay in these funds has harmed URI by impacting financial support to our earliest career scientists: our undergraduate researchers, our graduate students and our early career faculty. They hamper our ability to continue to lead to healthy outcomes for human populations of Rhode Island and in the US.

11. URI will not be able to provide funding for these projects without the NIH funds.

Comparisons Across Administrations

12. In prior years, delays in funding were exceedingly rare.

Conclusion

13. NIH grant delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.



Bethany Diane Jenkins

Date: 4/12/2025

EXHIBIT 61

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

SUPPLEMENTAL DECLARATION OF JEREMY M. BERG, PH.D.

I, Jeremy M. Berg, declare as follows:

Background

1. I am a former director of the National Institute of General Medical Sciences (NIGMS), one of the twenty-seven National Institutes of Health (NIH). I served as director of NIGMS from 2003 to 2011. The purpose of NIGMS is to support research and training of scientists across a wide range of areas, including biochemistry, cell biology, genetics, computational biology, bioinformatics, anesthesiology, wound healing, and burn and trauma research. The United States' ability to effectively treat, diagnose, manage, and ultimately cure diseases requires an understanding of their underlying mechanisms and biology. NIGMS' investments in fundamental basic research have supported 90 Nobel prizes and improvements in treatments for diseases including heart disease, cancer, neurological diseases associated with aging, sepsis, and many others.

2. Throughout my career, I have also helped guide scientists at the beginning of their independent careers as they sought to compete for NIH funding. Prior to coming to NIH, I was Director of the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins

University School of Medicine. In this role, I conducted research in partnerships with graduate students including combined MD/PhD students, and postdoctoral fellows with much of this work supported by NIGMS and other NIH institutes.

3. In 2011, I left NIH in 2011 to come to the University of Pittsburgh with my wife, a leading breast cancer screening expert who was recruited to this institution. Here, I have continued to conduct some NIH-funded research in the area of computational biology and also have helped to manage a range of programs that receive NIH funding.

4. Since January 20, 2025, delays and terminations in NIH funding have dramatically disrupted the work of advancing biomedical research and training the next generation of scientists. Steps that have contributed to these disruptions have included the "pausing" of grant-making processes at NIH, the extremely slow release of continuing awards for multi-year grants, the disruption of the regularly scheduled national Advisory Committee meetings required to approve grant applications prior to funding, the disruption of the peer review "study section" meetings required for grant application evaluation and prioritization, and other steps. More recently, these have included direct terminations of specific grants based not on lack of performance or any other irregularities, but claims that the aims of these grants no longer aligned with NIH's priorities. As described below, the gap in funds that would have typically been disbursed by this point in the year has continued to worsen.

Delays in NIH Grant Making and Funding

5. On April 2, 2025, I submitted a declaration based on my personal analysis of publicly available data (through the NIH Reporter website), stating that over $3.3 billion of NIH funding that would typically have been disbursed through NIH's grant making and grants management process by March 1, 2025 has not been. Through March 1st, more than $1.8 billion

of the funding is missing from the normal funding of continuation awards for multi-year grants. Similarly, more than a billion of the funding is missing in new grant funding from grant applications that undergo the highly competitive scientific peer review described in my previous declaration.

6. The NIH Reporter website is updated on a continuing basis with a lag time of approximately 1 week between the issuance of Notices of Award and appearance of information in NIH Reporter. Most NIH awards have budget start dates at the first of a month. I am therefore writing to supplement my original analysis to include awards that would have been expected through grants with April 1st budget start dates. Through April 7th, more than $1.6 billion is missing from the funding that would be anticipated from continuation awards for multi-year grants. In addition, more than $500 million is missing in new grant funding from grant applications that undergo the highly competitive scientific peer review described in my previous declaration, based on comparison with the level of new grants awards from this same period from previous fiscal years.

7. If these estimates were broken down on a week-to-week basis (i.e., weeks in 2024 compared to weeks in 2025), the estimated difference is stark. In Weeks 4-11 of 2024 (i.e., January 20, 2024, through March 14, 2024), NIH awarded a total of $4.08 billion with 8,071 awards. For comparison, in Weeks 4-11 of 2025 (i.e., January 20, 2025 through March 14, 2025), NIH awarded a total of $2.45 billion with 4,961 awards. This represents-a reduction of approximately 40%.

8. Narrowing the focus to new awards (and competitive renewal awards) that require study section and advisory council review prior to the award, in those same weeks, NIH awarded $740 million in 1,756 awards in 2024 but only $360 million in 781 awards in 2025. Focusing

further still just on Weeks 6-11 (February 3rd to March 14th), the comparison is even more striking: 1,342 awards for $576 million in 2024, compared with 395 awards for $180 million in 2025, a reduction of approximately 69%.

9. In a recent analysis, which includes awards with April 1st budget start dates, the estimated difference for Weeks 12-13 (i.e., the period from March 14, 2025 to April 1, 2025) is $1.04 billion. Of this, $780 million is due to non-competitive renewal awards that were anticipatable during this period—since many grants were due for renewal by April 1, 2025. In addition, based on the new and competitive renewal awards made during this same period in 2023 and 2024, I estimate that there is a $260 million reduction in anticipatable new and competitive renewal awards in 2025.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on this 14th day of April 2025, in Chicago, IL.

Jeremy M. Berg, Ph.D.
Former Director (2003-2011)
National Institute of General Medical Sciences
National Institutes of Health

EXHIBIT 62

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

SUPPLEMENTAL DECLARATION OF GANESH RAMAN, Ph.D.

I, **Ganesh Raman, Ph.D.**, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated here or have knowledge of the matters based on my review of information and records gathered by me and my colleagues at California State University ("CSU"). If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by California State University as the Assistant Vice Chancellor for Research.

3. I submit this Declaration in support of the States' Motion for a Preliminary Injunction.

4. On April 2, 2025, I signed a Declaration in support of the States' Motion for a Temporary Restraining Order. The current declaration is submitted to supplement that document.

5. Since I prepared my original declaration, researchers at CSU campuses have continued to receive notices of termination from NIH. I have reviewed data provided to me by the Chief Research Officers at the CSU university campuses and the total NIH grant monies at issue for the California State University and its auxiliary organizations is approximately $20.2 million in unspent grant funds.

6. Researchers at CSU university campuses have seen an unusual number of delays in the processing of NIH grant applications. Examples of these delays include:

a. At California State University, Fresno, a researcher submitted a grant in November 2024 with a decision date by the end of May 2025 and a start date of July 1, 2025. NIH grants have two levels of review: the scientific review meeting followed by the council review. The scientific review meeting was originally scheduled in February 2025 (with no specific date). This date has changed several times and presently no meeting date is listed. The council review meeting was scheduled in May 2025 but was recently changed to August 2025. This delay will not permit the grant to move forward as scheduled on July 1, 2025. (See Declaration of Marcus Crawford, Ph.D. at ¶6.)

b. At San Francisco State University, a researcher submitted a grant proposal on January 16, 2025 with a decision date by October 2025 and a start date of December 1, 2025. The scientific review meeting was originally scheduled in April 2025. The scientific review was delayed to July 2025. The council review was scheduled for October 2025. An important factor is that in 2024 there were 6 standing scientific review panels, now in 2025 there is only one scientific review panel, which can affect the fair evaluation of the proposal. In addition, the proposal was written and submitted with review guidelines and criteria that has since been changed after the grant has been submitted. (See Declaration of Blake Riggs, Ph.D. at ¶6.)

7. These delays in scheduling prevent the researchers from planning for the implementation of the grants and stall important research programs from moving forward.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed this 13th day of April, 2025, in Long Beach, California.



Ganesh Raman, Ph.D.
Assistant Vice Chancellor for Research
California State University

EXHIBIT 63

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-_____

DECLARATION OF BLAKE RIGGS, Ph.D.

I, Blake Riggs, Ph.D. declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am a resident of the State of California. I am over the age of 18 and have personal knowledge of all the facts stated here. If called as a witness, I could and would testify competently to the matters set forth below.

2. I am currently employed by San Francisco State University as an Full Professor and have held that position since January 3, 2010.

3. My current responsibilities include but are not limited to acting as the Principal Investigator for the *ER-Driven Asymmetric Cell Division: Mechanisms Underlying Cell Fate Determination in Drosophila Neurogenesis* proposal submitted to the National Institutes of Health ("NIH").

4. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

5. *ER-Driven Asymmetric Cell Division* is a 5-year grant. The goal of the research is to determine how internal cell structures and signals control what kind of cells are made. This research could also shed light on certain human diseases linked to problems with the JAGN1 gene, like severe congenital neutropenia.

6. The grant proposal was submitted on January 16, 2025 with a decision date by October 2025 and a start date of December 1, 2025. NIH grants have two levels of review: the scientific review meeting followed by the council review. The scientific review meeting was originally scheduled in April 2025. The scientific review was delayed to July 2025. Currently, the scientific review meeting is set for July 2025. The council review was scheduled for October

2025. An important factor is that in 2024 there were 6 standing scientific review panels, now in 2025 there is only one scientific review panel, which can affect the fair evaluation of the proposal. In addition, the proposal was written and submitted with review guidelines and criteria that has since been changed after the grant has been submitted.

7. The delay in scheduling negatively impacts moving the research forward and funding graduate students. Additionally, there are other grants at NIH and NSF that I could apply for but need to wait until this is reviewed and my score is provided. This delay greatly slows the research efforts.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on April 14, 2025, in San Francisco, California.



4/14/25

Blake Riggs, Ph.D.

EXHIBIT 64

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No. 1:25-cv-10814-BEM

DECLARATION OF SHASHANK PRIYA

I, Shashank Priya, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

1. I am the Vice President for Research and Innovation at the University of Minnesota (the "University"). The University's flagship campus is located in Minneapolis/St. Paul and there are four other campus locations in Minnesota. I have held this position since September 2022. Prior to that time, I served as Associate Vice President for Research at The Pennsylvania State University.

2. As Vice President for Research and Innovation, I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by University of Minnesota personnel. I offer this declaration in support of the request of the States' Motion for a Preliminary Injunction.

3. On February 17, 2025, I executed a declaration in support of judicial relief in the matter of *Association of American Universities, et al. v. Department of Health & Human Services, et al.*, Case No. 1:25-cv-10346. That declaration is attached as Exhibit 1 to this

Declaration and details the substantial funding received by the University from NIH and provides examples of the critical and cutting-edge medical research performed due to this funding. The declaration also details the potential impacts of a reduction in funding, which apply as well to the termination, suspension, and other delays relating to individual NIH grants.

4. There is also impact from NIH's delay and/or cancellation of study sections. NIH's abrupt cessation of NIH Advisory Council meetings in February 2025 has created a situation whereby significant numbers of grant proposals due for funding have remained unfunded for at least one grant cycle, and potentially indefinitely. These are grants that had previously been evaluated by the relevant scientific peer-review committee or "study section" (also known as scientific review group, initial review group) and given a priority score (based on scientific merit) that traditionally is within a range that would result in the awarding of the grant funds. These ranges are based on the recent history of similar grants funded by the same institute/center within NIH.

Terminations of NIH Grants

5. Since March 10, 2025, the University has had 21 NIH grants and subawards terminated.

6. These terminations will result in the loss of approximately $8.5 million in research money to the University.

7. The termination notices for these grants have provided vague reasons for the terminations, including noting that the research no longer "effectuates agency priorities." In my time working at the University, I have not seen this language previously used to terminate grants.

8. For many of the grants, the termination notices have also stated that there is no corrective action that can be taken to ensure the grant aligns with agency priorities. In those

cases, prior to receipt of the termination, the University had not been given notice of any opportunity to submit any "corrected" grant materials to align with agency priorities. Nor was the University provided with any updated "agency priorities" with which its research must align.

Irreparable Harm

9. The delays have disrupted ongoing research, as well as setting back the University for research going forward. The University will soon have to make decisions about which of these valuable programs to continue.

10. Some of these studies involve clinical trials for life-saving medications or procedures, and their closure would endanger the lives of patients. For example, the University is a major partner in the NIH U01 Diabetes Prevention Outcomes Study (DPPOS), serving as the central biochemistry lab for twenty-five clinical sites and serving on the project's Steering Committee. This project addresses the National Alzheimer's Project Act goal to "prevent, halt or reverse Alzheimer's Disease" in the high-risk group of persons with pre-diabetes and type 2 diabetes, who represent over half of the population aged 60 years or older in the United States.

11. Delays have also disrupted community services, student opportunities, and public programs.

12. In many cases, there is no way to recover the lost time, research continuity, or training value once disrupted.

Conclusion

13. The breakdown in NIH processes is affecting institutional operations, planning, and public health partnerships. Terminations and delays with no explanation or remedy are undermining confidence in the system. These harms are ongoing and, in many instances, irreparable.

/Shashank Priya

Shashank Priya

Date: April 24, 2025

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSSETTS

ASSOCIATION OF AMERICAN UNIVERSITIES, AMERICAN COUNCIL ON EDUCATION, ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES, BRANDEIS UNIVERSITY, BROWN UNIVERSITY, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, THE CALIFORNIA INSTITUTE OF TECHNOLOGY, CARNEGIE MELLON UNIVERSITY, THE UNIVERSITY OF CHICAGO, CORNELL UNIVERSITY, THE GEORGE WASHINGTON UNIVERSITY, JOHNS HOPKINS UNIVERSITY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, UNIVERSITY OF ROCHESTER, and TRUSTEES OF TUFTS COLLEGE, Plaintiffs, v. DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, DOROTHY A. FINK, M.D. in her official capacity as Acting Secretary, Department of Health and Human Services, and MATTHEW J. MEMOLI, M.D., M.S. in his official capacity as Acting Director, National Institutes of Health, Defendants.	Case No. 1:25-cv-10346 **DECLARATION OF SHASHANK PRIYA**

I, Shashank Priya, declare as follows:

1. I am the Vice President for Research and Innovation at the University of Minnesota (the "University"). The University's flagship campus is located in Minneapolis/St. Paul and there are four other campus locations in Minnesota. I have held that position since

September 2022. Prior to that time, I served as Associate Vice President for Research at The Pennsylvania State University.

2. As Vice President for Research and Innovation, I have personal knowledge of the contents of this declaration, or have knowledge of the matters based on my review of information and records gathered by University of Minnesota personnel. I offer this declaration in support of the request of the Association of American Universities (AAU) for judicial relief from the directive issued by the National Institutes of Health (NIH) on February 7, 2024: Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068).

3. The University of Minnesota receives substantial annual funding from the NIH. In the University's fiscal year 2024 alone, the University received 808 awards directly from NIH which obligated funding to the University of approximately $355.6 million. In addition, the University received NIH subawards from other entities. Awards received are distinct from expenditures incurred.

4. In any given fiscal year, the University of Minnesota is reimbursed for its expenditures on grants that were awarded in that year as well as in preceding years. In fiscal year 2024, the University of Minnesota was reimbursed by NIH for a total of $497.8 million from NIH direct awards and pass-through awards from other entities on which NIH was the prime funder (subawards). Of that, $135.9 million covered allowable indirect costs.

5. Recovery of the University's indirect costs is based on predetermined rates that have been contractually negotiated with the federal government. The University receives indirect costs calculated on a portion of its total direct costs referred to as "Modified Total Direct Costs" (MTDC).

6. Through fiscal year 2028, the University's negotiated indirect cost rate is 54% MDTC for on-campus research activities, 37% MTDC for other sponsored activities, 59% MTDC for the Hormel Institute, and 26% MTDC for all off-campus activities.

7. The impact of any significant reduction in the indirect cost rate would be devastating. For example, for fiscal year 2024, instead of $135.9 million in NIH reimbursement for indirect costs, a 15% MTDC cap on indirect costs would have resulted in the University receiving only $38.4 million in indirect costs. This would have been a loss of $97.5 million in one fiscal year.

8. Over the next five years, the University of Minnesota anticipates approximately $157.7 million in annual indirect costs based on the University's negotiated indirect cost rate. If—contrary to what the University of Minnesota has negotiated with the federal government—the indirect cost rate is reduced to a cap of 15% MTDC, the University's anticipated annual indirect cost recovery for NIH awards would be reduced by 71.8%, an average loss of $113.2 million per year over five years. This could result in a loss to the University of more than $565.7 million from fiscal year 2025 through fiscal year 2029.

9. The funding the University of Minnesota receives from NIH supports critical and cutting-edge medical research, which millions of Americans benefit from and depend on. For example:

a. **Cancer Research**: The University's cancer research includes the Cancer Center Support Grant (P30CA077598), which funds the Masonic Cancer Center to advance cancer prevention, detection, and treatment. This grant enables the development of innovative approaches to suppress the disease at its earliest

stages and fosters collaboration through shared resources and administrative support.

b. **Immunotherapy Research**: The University's immunotherapy research includes the Off-the-Shelf Immune Effector Cells for Hematological Malignancies (P01CA065493), which focuses on developing accessible and effective natural killer (NK) cell therapies for treating blood cancers. These therapies aim to improve patient outcomes by leveraging the immune system's ability to target cancer cells.

c. **Cancer Immunology Research**: The University's cancer immunology research includes NK Cells, Their Receptors, and Cancer Therapy (P01CA111412), which explores the biology of NK cells and their receptors to develop effective cancer therapies. This research seeks to harness NK cells' natural ability to detect and destroy cancer cells, offering new hope for treatment.

d. **Healthy Aging Research**: The University's healthy aging research includes the Minnesota Tissue Mapping Center for Senescent Cells (U54AG076041), which investigates the role of senescent cells in aging-related disorders. This research aims to develop interventions that promote healthier aging by identifying and targeting key mechanisms of cellular aging.

e. **Neurological Research and Imaging**: The University's neurological research (UM1NS132207 and P41EB027061)) leverages state-of-the-art ultra-high-field MRI instrumentation to study brain structure, function, and connectivity in unprecedented detail. This enables early detection of neurodegenerative

diseases (Alzheimer's, Parkinson's, ALS), mapping of brain function in psychiatric disorders (schizophrenia, depression, PTSD), and insights into brain plasticity and development (aging, traumatic brain injury, autism).

10. Indirect costs are essential for supporting this research. The NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize the research projects described in Paragraph 9.

11. Indirect costs include constructing and maintaining state-of-the-art facilities, such as laboratories, cleanrooms, and data centers, that meet the technical requirements of advanced research. They also cover the procurement and upkeep of essential equipment, such as ultra-high-field MRI machines, electron microscopes, advanced computing clusters, and specialized instrumentation for imaging, data analysis, and experimental setups. These investments ensure a safe and compliant environment for researchers to innovate, collaborate, and push the boundaries of discovery. Without these critical facilities and equipment, the research simply cannot be conducted, jeopardizing advancements that benefit society.

12. For example, with respect to the areas of research including those described in Paragraph 9:

a. **Cancer and Immunotherapy Research:** The University's advanced immunotherapy research, including cell-based therapies, relies on highly controlled manufacturing environments (GMP facilities) to ensure compliance with FDA Current Good Manufacturing Practices (cGMP). These facilities are essential for producing safe and effective immune-based treatments. A reduction in the F&A rate to 15% would severely underfund GMP operations, limiting production capacity, delaying patient access to novel treatments, and

jeopardizing quality control. This could increase costs, strain clinical trial infrastructure, slow development of next-generation therapies, and undermine the training of future scientists, ultimately reducing the University's ability to deliver cutting-edge therapies to patients and maintain global leadership in biomedical innovation.

b. **Healthy Aging Research:** Reduced funding due to a lower indirect cost rate could hinder data management, participant tracking, and multi-site diversity, leading to slower progress and diminished impact of these critical age-related interventions.

c. **Neurological Research and Imaging**: A 15% cap on indirect costs would severely impact the maintenance of MRI infrastructure, upgrades to advanced technology, and support for technical staff, leading to delays, data bottlenecks, and limited access to cutting-edge instruments. The massive datasets generated by high-field MRI research, often requiring petabyte-scale, HIPAA-compliant storage, would face funding shortfalls for secure and scalable solutions, increasing risks of data loss. Additionally, AI-powered MRI analysis, which relies on GPU clusters and cloud computing for early disease prediction, would be hampered by insufficient computing resources. These reductions would significantly impede progress in understanding and treating neurological disorders, undermining the University's leadership in MRI-based research and diagnostics.

13. Physical space costs are one of the largest components of indirect costs, and the amount of space available to researchers has a direct and obvious impact on the amount of research

that can be done at the University of Minnesota. The University's planned construction for the Minnesota Bioimaging Center, the BioTechnology and Biomanufacturing Innovation Center, and the Translational Research and Innovation Facility are critical to advancing life-saving research and clinical innovation. However, if a 15% cap on indirect costs were implemented, these projects would face significant delays or very likely cancellation of these projects, causing immediate and long-term harm not only to the University's research capabilities on life-saving technologies but also to the public health outcomes.

14. A critical component of this challenge lies in the facilities reimbursement structure. Facilities costs, which are based on depreciation and interest for investments already made to support research, are not variable costs that can be adjusted based on the volume of research. Over the past several decades, the University has made multi-decade investments totaling hundreds of millions of dollars in research infrastructure, including laboratories, imaging facilities, and advanced capabilities. These are sunk costs, not discretionary expenditures, and they represent essential commitments to supporting the research mission.

15. Changing the reimbursement structure after institutions have made these substantial investments is untenable. Good facilities planning hinges upon reliable and consistent funding sources; sudden and disruptive disturbances to prior funding commitments jeopardizes the financial sustainability of research facilities already in operation.

16. For instance, the Minnesota Bioimaging Center is designed to provide advanced imaging tools essential for understanding diseases such as cancer and chronic and infectious diseases at the molecular and cellular levels. Delays in the construction of this facility would impede researchers' ability to develop new diagnostics and therapies, slowing progress in precision oncology and other fields. The BioTechnology and Biomanufacturing Innovation Center is

designed to address key challenges in therapeutic development, biologics manufacturing, and scalable biomanufacturing processes by fostering collaborations between academic researchers, industry, and government stakeholders. Delaying the construction of this center would impede efforts to develop cutting-edge biologics and therapeutics, slowing the translation of research into scalable treatments and disrupting Minnesota's leadership in biotechnology and biomanufacturing innovation. Similarly, the Translational Research and Innovation Facility is essential for testing new therapeutics and advancing clinical trials. Delays in its completion would reduce the University's capacity to conduct early-phase trials and biomarker validation studies. This would directly impact the development pipeline for life-saving treatments, leading to longer timelines for FDA approval and reduced availability of new therapies for patients.

17. In addition to delaying new construction, the 15% cap would force institutions to reallocate funds to maintain existing facilities at the expense of research productivity and innovation. The depreciation and financing costs associated with decades-long infrastructure investments cannot simply be "turned off" or scaled down without jeopardizing research capacity. This structural shift in reimbursement undermines the foundational investments that make cutting-edge research possible.

18. The combined effect of these delays will hinder the University's ability to maintain its leadership in biomedical research and will negatively impact public health outcomes, patient care, and economic growth driven by biotech innovation. Without sufficient recovery of indirect costs, these crucial facilities and their potential contributions to medical science will remain unrealized.

19. In addition, indirect costs fund the administration of awards, including staff who ensure compliance with the regulatory mandates from agencies such as NIH. These mandates

serve many important functions, including protecting human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; preventing financial conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data.

20. A reduction in the indirect cost rate will have deeply damaging effects on the University's ability to conduct research from day one of an implemented change to existing and new awards. Most critically, it will necessarily and immediately result in staffing reductions across the board. For example:

> The University's clinical trials program relies heavily on indirect cost recovery to support specialized infrastructure, regulatory oversight, and patient engagement activities. Without appropriate funding, the institution would be forced to implement immediate reductions in essential staffing and resources, causing significant harm to research and patient care outcomes. For example, the University's Institutional Review Board (IRB) oversees the ethical review and compliance of all clinical trials, ensuring patient safety and adherence to federal regulations. A 15% cap on indirect costs would necessitate a reduction of staff members from the IRB. This reduction would delay the review of clinical trial protocols, hindering the timely initiation of critical studies, including early-phase trials for cancer therapies and precision medicine. These delays would also extend FDA approval timelines, slowing the availability of life-saving treatments. Similarly, patient recruitment and retention efforts

would be severely impacted. The University's patient navigator program, which supports rural and underserved populations in accessing clinical trials, would lose funding for navigators and outreach staff. This would result in a decline in recruitment from these populations, reducing trial diversity and generalizability of results. In rare disease and pediatric trials, which require long-term follow-ups and multisite collaborations, indirect cost reductions would force the University to cut back on the coordination staff and specialized research nurses critical to these efforts. This would make participation in multisite trials less viable, jeopardizing advancements in these highly vulnerable patient populations. Finally, the University's ability to ensure data security and deploy AI-driven trial monitoring systems—essential for real-time analysis and adverse event detection—would be impaired by reductions in cloud computing resources. This would increase risks to patient safety and trial reliability, further compromising research integrity.

21. The University has for decades relied on the payment of indirect costs. Until now, we have been able to rely on the well-established process for negotiating indirect cost rates with the government to inform our budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases. In some cases, University of Minnesota has long-term obligations for which it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

22. In addition to the immediate impacts and reliance interests described above, there are longer term impacts that are both cumulative and cascading.

23. The University's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. A massive reduction in the University of Minnesota's research budget would immediately and seriously jeopardize these contributions to the local region.

24. Finally, slowdowns or halts in research by the University of Minnesota and other U.S. universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance.

25. If required to absorb the cost of a reduced indirect cost rate, the University of Minnesota would be forced to immediately reduce key investments supporting the University of Minnesota's faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 17, 2025, at Minneapolis, Minnesota.

/s/ Shashank Priya
Shashank Priya

EXHIBIT 65

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., et al.,

Defendants.

No.1:25-cv-10814

DECLARATION OF HAROLD R. COLLARD

I, Harold R. Collard, declare as follows:

1. I am the Vice Chancellor for Research at the University of California, San Francisco ("UCSF") and a professor of Medicine and Health Policy. I am familiar with the information in the statements set forth below either through personal knowledge, in consultation with UCSF staff, or from documents that have been provided to and reviewed by me.

2. As Vice Chancellor for Research, I oversee UCSF's research mission. This includes responsibility for the institutional administrative units supporting federal contracts and awards. I have served as Vice Chancellor for Research at UCSF since September 2022.

3. As Professor of Medicine and Health Policy, I have conducted clinical research and written seminal articles on the epidemiology, natural history, and management of interstitial lung disease. I have trained dozens of clinical and translational research fellows, a number of whom are now leading academic research programs in interstitial lung disease around the world.

4. I submit this Declaration in support of the States' Motion for Preliminary Injunction.

Termination of NIH Research Awards Causes Irreparable Harm.

5. For nearly a decade, UCSF has been the top-funded public academic recipient of biomedical research funding from NIH. As a leading health sciences university, UCSF has 1,650 unique principal investigators with 4,110 active NIH awards. In fiscal year 2024, UCSF received approximately $792 million in funding from NIH.

6. Beginning in March 2025, UCSF began receiving a significantly increased number of award termination letters from the NIH. As of this date, UCSF has had 52 grants terminated by the NIH. The NIH letters notifying UCSF of award terminations have generally explained the terminations by saying that the funded research no longer aligns with the priorities of the agency. In my time as VCR, I have not seen NIH issue this number of award terminations, nor have I seen terminations based on a purported shift in agency priorities.

7. These award terminations are having a substantial impact on UCSF, its researchers, and the larger research community. The terminations have disrupted ongoing research in ways that directly impact the scientific integrity of the studies. And funding gaps resulting from award terminations are forcing researchers to abandon important research studies and to lay off key personnel.

8. When UCSF receives a research award from the NIH, the funds must be used to support the specific research project identified in the award consistent with the terms of the Award Notice. The award funds are used to support all aspects of the award, including personnel costs, drug and medication costs, technology and equipment. When an award is terminated, there are no longer any funds available to pay the salaries of the research staff or to cover significant expenses. When research staff are laid off, the institution loses the knowledge and

experience those research staff members possess and that was attained through the research project.

9. Canceling research projects at UCSF because of NIH award terminations will result in irreparable harm. Once canceled, most research projects cannot immediately resume. Many of these projects entail longitudinal studies. When scientific studies stop in full swing, their partial results often lose validity.

10. For example, on March 18, 2025, UCSF received a letter stating that funding for Project Number 1R01 AI186641-01was terminated because "[t]his award no longer effectuates agency priorities."

a. This Grant Award funded research studying the pharmacokinetics and pharmacodynamics of doxycycline in men and women, using urine, plasma, and hair drug-level measurement. Doxycycline is an effective treatment for chlamydia and syphilis and is a commonly used antibiotic for serious infections such as Staphylococcus aureus and Lyme disease. Understanding the metabolism of doxycycline is also relevant to the study of antimicrobial resistance, given that pharmacologic metrics of drug exposure are the only objective way to confirm antibiotic exposure after resistance has been detected in routine clinical settings.

b. The research project was being conducted through a randomized clinical trial that is currently 13% enrolled, with participants receiving doxycycline on a daily basis and submitting to the collection of urine, plasma and hair samples on a daily or weekly basis depending on timing since last dose to determine metabolic effects. Safety monitoring during and after dosing is critical to protecting the safety of participants

already enrolled. Doxycycline may cause liver injury and allergic reactions days to weeks after administration of the drug.

c. The Grant termination cancelled $618,496.47 in funding for year 1 and a total of $3,243,539 for future years. As a result, UCSF is preparing to lay off the staff members responsible for monitoring the participants' daily consumption of doxycycline, retrieving and reviewing the laboratory collection of urine, blood and hair samples, and is unable to pay salary owed to senior scientists responsible for analyzing the metabolic impacts of Doxycycline.

11. Another UCSF Grant terminated by NIH on March 10, 2025, was Project Number R01EY028739-07 which studied the impact of the Herpes Zoster (or shingles) vaccine on Herpes Zoster Ophthalmicus. The termination letter stated that the Grant award was no longer consistent with agency priorities.

a. Shingles affects one in three Americans during their lifetime and about 10-20% of those cases involve shingles of the eye and the surrounding nerves (herpes zoster ophthalmicus). This can be exceptionally painful and can result in permanent vision loss. The Grant studied the effectiveness of the shingles vaccine on herpes zoster ophthalmicus, including whether the vaccine could trigger another bout of shingles inflammation of the eye in those patients who previously experienced herpes zoster ophthalmicus which would caution against administration of the vaccine to such patients.

b. The Grant termination cancelled $ 2,161,532 in funding for this project. As a result, UCSF is preparing to lay off three full-time research data scientists and

also will be unable to pay the Principal Investigator to compensate her for time spent to conduct research (as opposed to time spent seeing patients as a Clinician).

13. A later award of money damages by a court cannot make up for the fundamental harms caused by NIH grant terminations that support ongoing biomedical research studies at UCSF.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct and that this declaration was executed this 14th day of April.

DocuSigned by:
Harold Collard
A3367CF03F8446A...

HAROLD R. COLLARD