

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



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>



National Institutes of Health
Office of Extramural Research

3/24/2025

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

Dear Nick Novak:

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

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

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

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

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

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

Administrative Appeal

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

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

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

Sincerely,

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

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

^[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)



Recipient Information	Federal Award Information																								
1. Recipient Name UNIVERSITY OF WISCONSIN SYSTEM 21 N PARK ST STE 6301 MADISON, WI 53715	11. Award Number 5R01AI158463-04																								
2. Congressional District of Recipient 02	12. Unique Federal Award Identification Number (FAIN) R01AI158463																								
3. Payment System Identifier (ID) 1396006492A1	13. Statutory Authority 42 USC 241 42 CFR 52																								
4. Employer Identification Number (EIN) 396006492	14. Federal Award Project Title Coronavirus RNA synthesis by multicomponent protein machines																								
5. Data Universal Numbering System (DUNS) 161202122	15. Assistance Listing Number 93.855																								
6. Recipient's Unique Entity Identifier LCLSJAGTNZQ7	16. Assistance Listing Program Title Allergy and Infectious Diseases Research																								
7. Project Director or Principal Investigator Robert N Kirchdoerfer, PHD Assistant Professor rnkirchdoerf@wisc.edu 608-262-6191	17. Award Action Type Non-Competing Continuation (REVISED)																								
8. Authorized Official Nick Novak preaward@rsp.wisc.edu 608-262-3822	18. Is the Award R&D? Yes																								
Federal Agency Information	<table border="1"><thead><tr><th colspan="2">Summary Federal Award Financial Information</th></tr></thead><tbody><tr><td colspan="2">19. Budget Period Start Date 08/01/2023 – End Date 03/24/2025</td></tr><tr><td>20. Total Amount of Federal Funds Obligated by this Action</td><td>\$0</td></tr><tr><td>20 a. Direct Cost Amount</td><td>\$0</td></tr><tr><td>20 b. Indirect Cost Amount</td><td>\$0</td></tr><tr><td>21. Authorized Carryover</td><td></td></tr><tr><td>22. Offset</td><td></td></tr><tr><td>23. Total Amount of Federal Funds Obligated this budget period</td><td>\$389,042</td></tr><tr><td>24. Total Approved Cost Sharing or Matching, where applicable</td><td>\$0</td></tr><tr><td>25. Total Federal and Non-Federal Approved this Budget Period</td><td>\$389,042</td></tr><tr><td colspan="2">26. Project Period Start Date 08/05/2020 – End Date 03/24/2025</td></tr><tr><td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td><td>\$1,738,787</td></tr></tbody></table>	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
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																								
9. Awarding Agency Contact Information Lindsey Ann Freeman NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES lindsey.kisliuk@nih.gov 301.761.6896	28. Authorized Treatment of Program Income Additional Costs																								
10. Program Official Contact Information Mary Katherine Bradford Plimack NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES kate.plimack@nih.gov (240) 447-9748	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.																									

**RESEARCH**

Department of Health and Human Services
National Institutes of Health

Notice of Award



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)

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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) 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.

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 (FAPIS)). 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

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.

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

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



Recipient Information	Federal Award Information																								
1. Recipient Name UNIVERSITY OF WISCONSIN SYSTEM 21 N PARK ST STE 6301 MADISON, WI 53715	11. Award Number 1P01AI165077-01																								
2. Congressional District of Recipient 02	12. Unique Federal Award Identification Number (FAIN) P01AI165077																								
3. Payment System Identifier (ID) 1396006492A1	13. Statutory Authority 42 USC 241 42 CFR 52																								
4. Employer Identification Number (EIN) 396006492	14. Federal Award Project Title PanCorVac (Center for Pan-Coronavirus Vaccine Development)																								
5. Data Universal Numbering System (DUNS) 161202122	15. Assistance Listing Number 93.855																								
6. Recipient's Unique Entity Identifier LCLSJAGTNZQ7	16. Assistance Listing Program Title Allergy and Infectious Diseases Research																								
7. Project Director or Principal Investigator YOSHIHIRO KAWAOKA, DVM Professor yoshihiro.kawaoka@wisc.edu 608-265-4925	17. Award Action Type New Competing (REVISED)																								
8. Authorized Official Brenda Egan nih@rsp.wisc.edu 608-262-3822	18. Is the Award R&D? Yes																								
Federal Agency Information	<table border="1"><thead><tr><th colspan="2">Summary Federal Award Financial Information</th></tr></thead><tbody><tr><td colspan="2">19. Budget Period Start Date 09/16/2021 – End Date 03/24/2025</td></tr><tr><td>20. Total Amount of Federal Funds Obligated by this Action</td><td>\$0</td></tr><tr><td>20 a. Direct Cost Amount</td><td>\$0</td></tr><tr><td>20 b. Indirect Cost Amount</td><td>\$0</td></tr><tr><td>21. Authorized Carryover</td><td></td></tr><tr><td>22. Offset</td><td></td></tr><tr><td>23. Total Amount of Federal Funds Obligated this budget period</td><td>\$7,000,324</td></tr><tr><td>24. Total Approved Cost Sharing or Matching, where applicable</td><td>\$0</td></tr><tr><td>25. Total Federal and Non-Federal Approved this Budget Period</td><td>\$7,000,324</td></tr><tr><td colspan="2">26. Project Period Start Date 09/16/2021 – End Date 03/24/2025</td></tr><tr><td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td><td>\$7,000,324</td></tr></tbody></table>	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
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																								
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	28. Authorized Treatment of Program Income Additional Costs																								
10. Program Official Contact Information JENNIFER L. Gordon Program Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES jennifer.gordon2@nih.gov 3017616805	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.																									



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

Notice of Award



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)

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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.

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) P01A1165077. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

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

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

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

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

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

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

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

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIS)). 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.

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)**.

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>

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/bmb15/bmb15toc.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:

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:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o 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

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

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.

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)



Recipient Information	Federal Award Information
1. Recipient Name UNIVERSITY OF WISCONSIN SYSTEM 21 N PARK ST STE 6301 MADISON, WI 53715	11. Award Number 5R01MD018571-02
2. Congressional District of Recipient 02	12. Unique Federal Award Identification Number (FAIN) R01MD018571
3. Payment System Identifier (ID) 1396006492A1	13. Statutory Authority 42 USC 241 42 CFR 52
4. Employer Identification Number (EIN) 396006492	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
5. Data Universal Numbering System (DUNS) 161202122	15. Assistance Listing Number 93.307
6. Recipient's Unique Entity Identifier LCLSJAGTNZQ7	16. Assistance Listing Program Title Minority Health and Health Disparities Research
7. Project Director or Principal Investigator Elliot Tebbe, PHD (Contact) tebbe@wisc.edu 320-339-9992	17. Award Action Type Non-Competing Continuation (REVISED)
8. Authorized Official Darlene Holte	18. Is the Award R&D? Yes
Federal Agency Information	Summary Federal Award Financial Information
9. Awarding Agency Contact Information Sy Shackelford NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES shackelfords@mail.nih.gov 301-402-1366	19. Budget Period Start Date 03/01/2025 – End Date 03/20/2025
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	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 \$1,454,524 Sharing or Matching this Project Period
30. Remarks	28. Authorized Treatment of Program Income Additional Costs 29. Grants Management Officer - Signature Priscilla Grant

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.

**RESEARCH**

Department of Health and Human Services
National Institutes of Health

Notice of Award



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

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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) 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.*

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 (FAPIS)). 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

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

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

WI Decl. of Grejner-Brzezinska,
Ex. D - 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](#)



National Institutes of Health
Office of Extramural Research

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

^[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)



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

\$4,567,357

Sharing or Matching this Project Period

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.



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

Notice of Award



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)

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.
- 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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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/>.

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 (FAPIS)). 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.

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

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

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