EXHIBIT 30

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS; et al.,

Plaintiffs,

v.

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

Defendants.

No. 1:25-cv-_____

DECLARATION OF MEGAN A. MORENO

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

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

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

Professional Background

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

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

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

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

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

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

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

Reliance on NIH Funding

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

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

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

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

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

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

Typical Timeline and Processes for NIH Grant Awards

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

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

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

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

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

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

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

Delays and Irregularities in the Processing of NIH Grant Applications

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

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

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

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

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

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

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

Irregularities in Grant Terminations

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

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

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

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

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

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

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

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

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

Comparisons Across Administrations

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

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

Impacts from NIH Funding Terminations and Delays and Irreparable Harm

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

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

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

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

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

Conclusion

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

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

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

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

WI Decl. of Moreno, Ex. A
4.2.2025

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

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

Recipient Information

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

MADISON, 53715

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

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

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

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

10. Program Official Contact Information
JAMES GRIFFIN

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

Federal Award Information

11. Award Number
1P01HD109850-01

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

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

15. Assistance Listing Number
93.865

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

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

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

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Sarah M Lee

(301) 435-2307

30. Remarks

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

Notice of Award

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1P01HD109850-01

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

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

Dear Authorized Official:

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

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

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

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

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

Sincerely yours,

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

Additional information follows

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

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

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

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

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

Fiscal Information:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Treatment of Program Income:

Additional Costs

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

Clinical Trial Indicator: No

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

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

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

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

Delayed Start Date

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

Escalation

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

Salary CAP

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

Subproject

Subproject funding information is available via the NIH RePORTER System.

Overlap

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

Human Subjects

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

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

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

COVID-19

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

SPREADSHEET SUMMARY
AWARD NUMBER: 1P01HD109850-01

INSTITUTION: UNIVERSITY OF WISCONSIN-MADISON

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

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

WI Decl. of Moreno, Ex. B
4.2.2025

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

3/21/2025

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

Dear Schulz, Christy R:

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

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

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

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

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

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

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

Administrative Appeal

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

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

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

Sincerely,

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

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

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

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

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

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

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

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

[7] *See* 2 C.F.R. § 200.343 (2024).

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

[9] *See* 45 C.F.R. § 75.374.

[10]

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

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

WI Decl. of Moreno, Ex. C
4.2.2025

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

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

Recipient Information

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

2. Congressional District of Recipient
02

3. Payment System Identifier (ID)
1396006492A1

4. Employer Identification Number (EIN)
396006492

5. Data Universal Numbering System (DUNS)
161202122

6. Recipient's Unique Entity Identifier
LCLSJAGTNZQ7

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

8. Authorized Official
CHRISTY R SCHULZ

Federal Agency Information

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

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

Federal Award Information

11. Award Number
5P01HD109850-03

12. Unique Federal Award Identification Number (FAIN)
P01HD109850

13. Statutory Authority
42 USC 241 42 CFR 52

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

15. Assistance Listing Number
93.865

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

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

18. Is the Award R&D?
Yes

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

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

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

Notice of Award

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5P01HD109850-03 REVISED

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

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

Dear Authorized Official:

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

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

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

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

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

Sincerely yours,

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

Additional information follows

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

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

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

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

IC	CAN	2024
HD	8014702	$1,484,126

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

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

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

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

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

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

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

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

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 (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

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

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

TERMINATION

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

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

WI Decl. of Moreno, Ex. D
4.2.2025

Location

Status

- [x] Active
- [ ] Inactive

Reset

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

Sort by

Last Updated Date: New - Old

Showing 1 - 5 of 5 results

93.865 Child Health and Human Development Extramural Research

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

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Feb 27, 2025

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

93.361 Nursing Research

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

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

+ History

Assistance Listing

Is Funded
Yes

Last Updated Date
Nov 18, 2024

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

93.977 Sexually Transmitted Diseases (STD) Prevention and Control Grants

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

Assistance Listing

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

93.978 Sexually Transmitted Diseases (STD) Provider Education Grants

Assistance Listing

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

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
CENTERS FOR DISEASE CONTROL AND PREVENTION

Last Updated Date
Nov 15, 2024

Type of Assistance
B-Cooperative Agreements

+ History

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

Assistance Listing

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

Is Funded
Yes

Dept / Ind Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF

Subtier
NATIONAL INSTITUTES OF HEALTH

Last Updated Date
Nov 11, 2024

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

+ History

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SAM.gov
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WI Decl. of Moreno, Ex. E
4.2.2025

Follow

ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

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

Overview

Objectives

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

Examples of Funded Projects

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

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

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

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

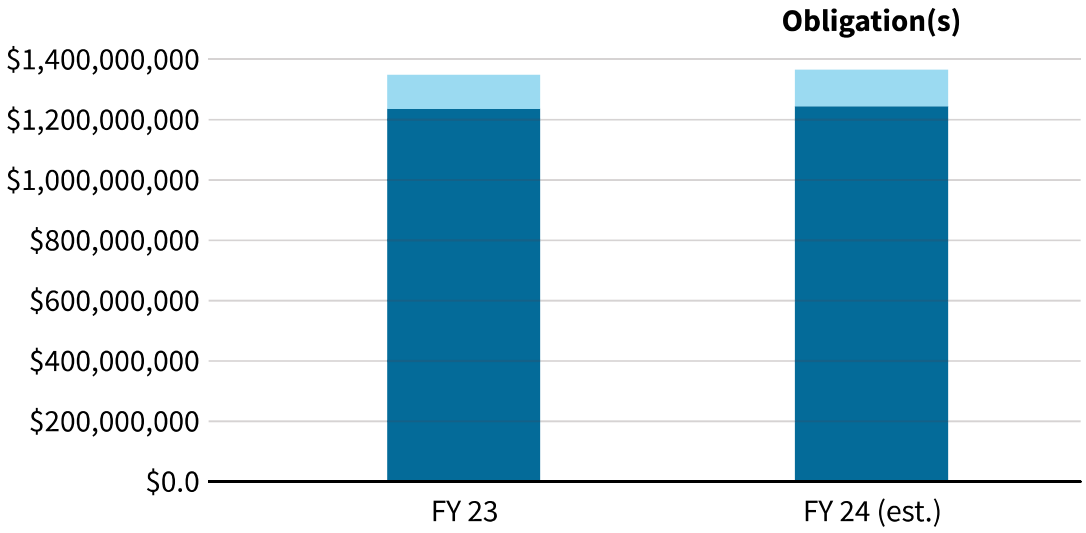
Authorizations

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

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

Financial Information

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



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

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

Range and Average of Financial Assistance

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

Accomplishments

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

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

Account Identification

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

Criteria for Applying

Types of Assistance

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

Credentials and Documentation

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

Applicant Eligibility

Designations

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

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

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

Beneficiary Eligibility

Designations

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

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

Length and Time Phasing of Assistance

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

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

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

Applying for Assistance

Deadlines

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

Preapplication Coordination

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

Application Procedures

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

Criteria for Selecting Proposals

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

Award Procedure

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

Date Range for Approval/Disapproval

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

Renewals

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

Appeals

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

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

Compliance Requirements

Policy Requirements

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

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

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

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

Additional Information:

Reports

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

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

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

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

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

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

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

Audits

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

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

Records

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

Regulations, Guidelines, and Literature

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

Formula and Matching Requirements

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

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

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

History

2025
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2024
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2023
Published
Child Health and Human Development Extramural Research

2022
Published
Child Health and Human Development Extramural Research

2021
Published
Child Health and Human Development Extramural Research

2020
Published
Child Health and Human Development Extramural Research

2019
Published
Child Health and Human Development Extramural Research

2018
Published
Child Health and Human Development Extramural Research

2004
Title Changed
Child Health and Human Development Extramural Research

1998
Title Changed
Center for Research for Mothers and Children

1990
Number Changed
Number changed from 13.865

-
Published
Research for Mothers and Children

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ASSISTANCE LISTINGS

Child Health and Human Development Extramural Research

Assistance Listing

Popular Name
Child Health and Human Development

Sub-tier
NATIONAL INSTITUTES OF HEALTH

Assistance Listing Number
93.865

Related Federal Assistance
Not Applicable.

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

Overview

Objectives

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

Examples of Funded Projects

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

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

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

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

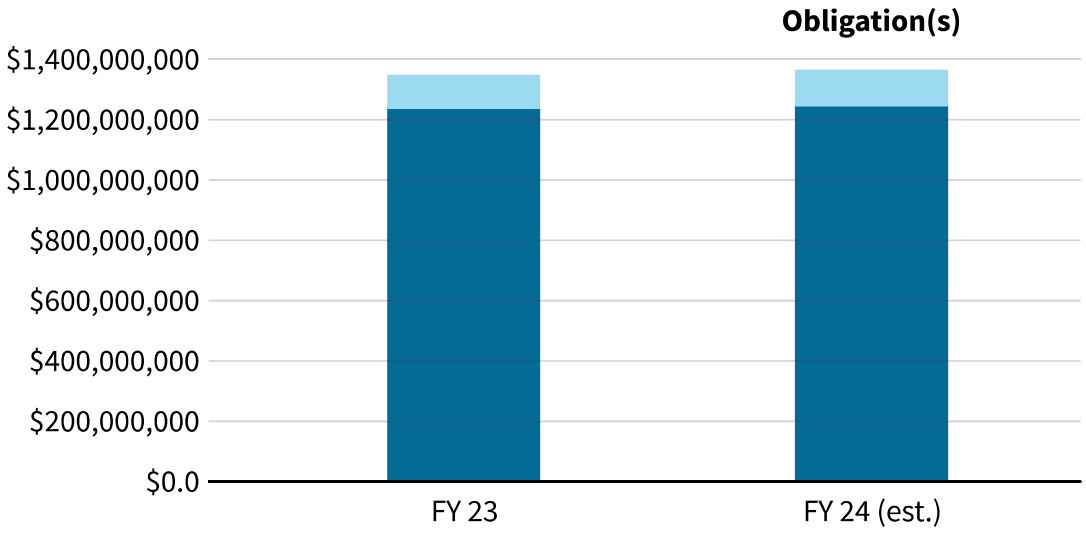
Authorizations

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

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

Financial Information

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



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

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

Range and Average of Financial Assistance

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

Accomplishments

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

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

Account Identification

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

Criteria for Applying

Types of Assistance

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

Credentials and Documentation

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

Applicant Eligibility

Designations

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

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

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

Beneficiary Eligibility

Designations

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

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

Length and Time Phasing of Assistance

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

Use of Assistance

Designations

Health/Medical, Higher Education (includes Research)

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

Applying for Assistance

Deadlines

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

Preapplication Coordination

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

Application Procedures

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

Criteria for Selecting Proposals

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

Award Procedure

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

Date Range for Approval/Disapproval

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

Renewals

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

Appeals

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

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

Compliance Requirements

Policy Requirements

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

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

Subpart D, Post Federal; Award Requirements

Subpart E, Cost Principles

Subpart F, Audit Requirements

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

Additional Information:

Reports

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

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

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

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

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

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

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

Audits

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

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

Records

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

Regulations, Guidelines, and Literature

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

Formula and Matching Requirements

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

Contact Information

Regional or Local Locations:

None.

Headquarters Office:

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