

AMERICAN CIVIL LIBERTIES UNION FOUNDATION

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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

ARGHAVAN SALLES; ABIGAIL HATCHER;
ANDREA ROSSO; ANN D. COHEN-WILSON;
DOLORES ALBARRACÍN; HEIDI MOSESON;
JADE PAGKAS-BATHER; JONATHAN KYLE
DAW; KATIE EDWARDS; KELTON MINOR;
MICHAEL D. GREEN; SARA JACKSON;
SUZANNE BELL; JORDAN DOE 1; JORDAN DOE
2; JORDAN DOE 3; and JORDAN DOE 4, *on behalf
of themselves and all others similarly situated,*

Plaintiffs,

v.

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

Defendants.

Case No. 3:26-cv-10510-SK

**DECLARATION OF
KATIE EDWARDS**

* Application for *Pro Hac Vice* Admission Forthcoming

** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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FOUNDATION OF NORTHERN CALIFORNIA**

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* Application for *Pro Hac Vice* Admission Forthcoming

1 I, Katie Edwards, declare:

2 1. I have personal knowledge of the facts set forth in this declaration, and if called to testify
3 as a witness thereto, could do so competently under oath.

4 2. I am a Professor of Social Work at the University of Michigan. My research focuses on
5 preventing sexual and related forms of violence among minority communities by using evidence-based,
6 affirming, and culturally-grounded approaches. My current work is focused on program development
7 and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth. In 2025, I was
8 named by Stanford University as one of the top two percent researchers in the world, and ranked 25th
9 out of 13,543 researchers in the field of criminology. In my lab, we have some of the first studies ever to
10 show we have reduced violence and alcohol use among LGBTQ+ youth as well as sexual violence
11 among Indigenous youth.

12 3. I offer this declaration in my individual capacity and not on behalf of my employer.

13 4. My interest in this area of work began during my undergraduate studies. Through my
14 studies and volunteer work, I saw the damaging effects of sexual violence and other forms of violence,
15 and I wanted to learn how to prevent violence from happening in the first place. While most of my work
16 in graduate school focused on college students, early on in my career as an assistant professor, I realized
17 that most of the scientific literature at the time did not address the particular needs of LGBTQ+ youth, a
18 glaring gap especially given that this demographic experiences disproportionately higher rates of sexual
19 and other forms of violence. My passion grew from wanting to work to help all youth who were
20 experiencing these harms and especially youth experiencing high rates of violence about whom we as a
21 field had done relatively less research.

22 5. Before working at the University of Michigan, I was a Professor of Educational
23 Psychology at the University of Nebraska-Lincoln. Before that, I was an Assistant and Associate
24 Professor of Psychology at the University of New Hampshire.

25 6. I received my B.S. in Psychology in 2005 from the University of Georgia. I completed
26 my Ph.D. in Clinical Psychology at Ohio University in 2011, and I received a graduate certificate in
27 Women and Gender Studies from Ohio University that same year.

1 7. To date, I have published more than 240 peer-reviewed journal articles, which were made
2 possible, in part, through obtaining more than \$25 million in research funding over the course of my
3 career.

4 8. I have applied for and received 13 grants from the National Institutes of Health (NIH)
5 over the course of my career. The application process for each grant was a lengthy and involved one, but
6 that process—at least until recently—helped ensure that the most rigorous and impactful research is
7 conducted. In my experience, preparing an application requires months, if not years, of work—from
8 pilot studies, literature review or other background research, to input from community partners and
9 fellow researchers, to honing methodological design—and often new studies will build off of the work
10 and findings from previous studies.

11 9. I am a plaintiff in the lawsuit *American Public Health Association v. National Institutes*
12 *of Health*, No. 1:25-cv-10787 (D. Mass.). Several of my grants and research applications were the
13 subject of the lawsuit. The grant applications discussed in this declaration are separate from the grants
14 and applications that are at issue in that lawsuit.

15 10. I have had at least one grant application—an application for an R21 grant—for which I
16 have been told by NIH to remove certain words or concepts from the scope of my intended work. Our
17 goal with this study is to evaluate the impact of a sexual violence prevention program for youth living on
18 or near the Pine Ridge Indian Reservation.

19 11. Through previous work, we developed a program that served K-12 Indigenous youth,
20 with the goal of developing skills to reduce and prevent instances of sexual violence. The program was
21 tailored to the developmental needs of different age groups. For example, students in third through fifth
22 grade were grouped into the same program, where they learned skills like how to seek help from adults
23 if someone is hurting them. As another example, high school students were also grouped in one of two
24 classes, with high school girls getting lessons on empowerment self-defense, including verbal and
25 physical resistance strategies, and high school boys received lessons on bystander intervention, sexual
26 consent, and gender equity. There were six classes for each age bracket, and each class met once a week
27 for two hours. In total, around 650 students in schools on or near the Pine Ridge Indian Reservation
28 participated in this program, and we collected data in the form of surveys to measure the efficacy of this

1 program. However, we have not yet been able to thoroughly analyze the data we have collected due to
2 limited funding; new funding would permit staff to spend dedicated time processing and analyzing the
3 data, as well as allow us to hire a biostatistician to spend time dedicated to this project.

4 12. The goal of the R21 grant application is to evaluate the impact of this program using the
5 data that has been collected. Funding from this grant would go towards the time and labor to clean and
6 analyze the data and disseminate the findings. That would allow us to better understand the efficacy of
7 the program, which demographic subgroups benefitted from this program, and whether and how the
8 program could be implemented more broadly to benefit other Indigenous youth and communities. In
9 addition, conducting these analyses would benefit the members on the team who would be able to
10 disseminate the findings of this research in peer-reviewed journals, helping not only spread this
11 information to the broader scientific community but also supporting their career trajectory and
12 supporting more meaningful engagement with Tribal community members.

13 13. We submitted the R21 application in June 2025. Putting together this application took a
14 significant amount of time, totaling hundreds of hours over months across members of our team.

15 14. In February 2026, we received our summary statement for this application. In July 2026,
16 I emailed the program officer assigned to the application to meet to discuss it, and around that time, the
17 status of my application on eRA Commons changed from “Council Review Completed” to “Pending.”

18 15. On August 6, 2026, I met with my program officer to discuss this application. During that
19 meeting, she told me that I could not use the term “gender” in the application, and that instead I should
20 change the word “gender” to “biological sex.” Following that meeting, later that day, I received an
21 official request from NIH to submit Just-in-Time information for the application.

22 16. On August 10, 2026, the program officer assigned to my grant emailed me about the
23 status of the grant application. Attached hereto as Exhibit 1 is a true and correct copy of that email.
24 According to the program officer, “[t]he purpose of [that] email is to resolve any administrative issues
25 that may delay the release of a Notice of Award should we be able to fund your application pending
26 final NICHD leadership and budgetary review.” Ex. 1 at 1. In that email, the program officer also stated:
27 “To ensure alignment with Administration priorities, please adjust the term gender in the abstract and
28 specific aims when referring to biological sex. Use the attached word document template for the edits,

1 and have your [Authorized Organization Representative] submit the edits via email, back to me.”
2 Attached hereto as Exhibit 2 is a true and correct copy of the Word document template attached to that
3 email.

4 17. Following this conversation and email with my program officer, I revised the application
5 materials for this R21 grant application, changing the word “gender equitable attitudes” to “healthy
6 attitudes.” I did not and do not believe that the term “biological sex attitudes,” instead of “gender
7 equitable attitudes,” meaningfully or accurately describes the scope of our work. In addition, I revised
8 the application materials to change standalone uses of the word “gender” to “biological sex.” On
9 September 18, 2026, NIH issued a notice of award (NOA) for this grant (R21HD122186). Attached
10 hereto as Exhibit 3 is a true and correct copy of that NOA.

11 18. In light of these interactions with the program officer assigned to this grant application,
12 as well as the priority statements issued by NIH since 2025, including in August 2025 and December
13 2025, I am concerned that the revisions to my application will limit the scope and scientific accuracy of
14 our analyses, publications, and findings. Some of the youth in our study identify as Two Spirit,
15 transgender, or nonbinary, and restrictions on the use of the term “gender” may prevent us from fully
16 examining and reporting their experiences, meaning that we will not as fully be able to analyze the
17 impact of the program on these populations. More broadly, gender is central to the study and prevention
18 of sexual violence. Gender socialization, gender norms, and attitudes about gender and gender equity are
19 among the factors that can shape sexual violence and are directly relevant to understanding how and
20 why prevention programs work. Replacing a concept such as “gender equitable attitudes” with “healthy
21 attitudes” changes its meaning and makes it more difficult to accurately describe and evaluate the
22 mechanisms our intervention is designed to address. These restrictions could therefore cause our
23 analyses to miss important differences and nuances in how youth experience and respond to the
24 intervention and limit our ability to understand for whom and how the program works, which in turn
25 limits the scope of the recommendations that can be used to better public health. I am concerned that this
26 will both exclude or obscure the experiences of populations who may particularly benefit from this
27 research and reduce the scientific quality and usefulness of the findings. And I am worried about being
28

1 able to describe any work funded by this grant in publications or presentations in a manner that is
2 inconsistent with the language that NIH forced me to adopt in my application materials.

3 19. In addition, I have at least one R01 grant application that I have not resubmitted because
4 of the actions NIH has taken against disfavored viewpoints. The research that would be funded by this
5 grant application builds off the findings and research coming out of a successful R34 grant, titled
6 Development and Pilot Evaluation of an Online Intervention to Prevent Dating Violence and Problem
7 Drinking in Sexual Minority Youth. Through that R34 grant, my team developed and evaluated a new
8 intervention program (called the Promoting Resilient Youth and Strong Hearts and Minds program),
9 which provided online support and skill building to LGBTQ+ youth. The program consisted of one-hour
10 weekly sessions for nine weeks, where 2 LGBTQ+ adults would lead group sessions with 10-15
11 LGBTQ+ youth. Topics covered during these sessions included positive identity development,
12 debunking myths and dispelling stigma around being LGBTQ+, and building skills such as regulating
13 emotions and handling conflict. Our results showed that this type of program was an efficacious
14 intervention to reduce teen dating violence, alcohol use, and alcohol consequences in LGBTQ+ youth,
15 and findings from this work were published in the *Journal of Studies on Alcohol and Drugs*, a leading
16 peer-reviewed journal.

17 20. As is the standard scientific progression following a successful R34 grant, we submitted
18 an R01 application in early February 2025 to build on our prior work. Our goal with an R01 was to
19 evaluate the efficacy of the program in a larger sample, examine whether effects from the program
20 differed across demographic subgroups, and better understand how and why the program was producing
21 reductions in dating violence, alcohol use, and related harms in youth. Our goal was also to follow
22 participants for a substantially longer period, extending follow-up from 3 months in the R34 study to 18
23 months in the R01, which would allow us to determine whether the program's effects were sustained
24 over time.

25 21. In July 2025, NIH informed us that our application had been denied. The peer reviewers
26 recognized the significance and public health importance of the project, the strength of the pilot
27 findings, the expertise of the investigative team, and additional strengths of the proposed study. The
28 reviewers consistently recognized the need for an evidence-based intervention addressing teen dating

1 violence and alcohol use among LGBTQ+ youth and viewed the pilot findings from the R34 research as
2 promising. The principal critiques focused on methodological issues—including statistical modeling,
3 implementation details, and aspects of the analytic plan—that are readily addressable in an R01
4 resubmission, rather than fundamental concerns about the intervention itself or its scientific merit.

5 22. Under ordinary circumstances, I would have revised the R01 application and submitted a
6 revised R01 proposal. However, following the initial submission of this application, the federal funding
7 environment for research involving LGBTQ+ populations has changed substantially, appearing to target
8 and forbid studies explicitly including transgender and gender-diverse youth. Based on my experience as
9 an NIH-funded investigator and the changes I observed in NIH funding priorities and decision, along
10 with the public guidance issued by NIH in August 2025 and December 2025, I believe that the
11 likelihood of successfully obtaining funding for this R01 application in its intended form is extremely
12 low. My hesitation to resubmit this application is also informed by my experience of being told that I
13 must remove certain concepts from the other grant application discussed above. Especially in light of the
14 experiences discussed in this declaration, I am concerned that I would have to remove certain
15 demographic populations from the R01 application before resubmitting, such as transgender individuals,
16 nonbinary individuals, and racial and ethnic minorities. Doing so would not only exclude populations
17 who experience disproportionately high rates of dating violence and alcohol-related harms from research
18 intended to benefit them, but would also weaken the scientific value of the study by preventing us from
19 examining important differences and nuances in how the intervention works for youth with different
20 identities and experiences.

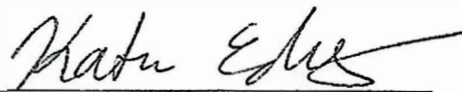
21 23. At this time, I am not sure whether I will resubmit this R01 application. Even if I do, the
22 application will not be as strong, and will not benefit as broad of a population, as it would be if I could
23 resubmit with the populations and terms targeted by the NIH.

24 24. I have never been so scared in my life about the future of our field and my work. Many of
25 our major grants are nearing an end, and in light of the current censorship by the NIH, I am concerned
26 about the ability to obtain enough funding to support my staff of approximately 50 individuals. I am also
27 concerned about the erasure of populations in public health—such as transgender, Two-Spirit, and
28 nonbinary individuals—who experience substance abuse, sexual assault, and dating violence at higher

1 rates than the general population, and who would therefore stand to benefit significantly from research
2 aimed at understanding and addressing those disparities. And at a personal level, I am concerned that,
3 even if I do receive funding with revised and more limited grant proposal, the restrictions required to
4 obtain that funding will compromise the scientific quality of our research. The restrictions required to
5 obtain that funding may prevent us from asking important research questions, examining meaningful
6 differences across populations, accurately studying factors such as gender that are central to
7 understanding and preventing violence, and fully reporting what our data show. These limitations would
8 ultimately reduce the usefulness and impact of the research and the publications that result from it,
9 hinder the development of effective prevention strategies, and reduce the positive impact of this research
10 on the health of LGBTQ+ youth and/or Indigenous youth.

11 25. I understand that, as a class representative, I represent the interests of everyone in the
12 class, and not just myself. I am prepared to stay informed about what is happening with my case and
13 stay in touch with my attorneys to give them information they need. I am committed to being a class
14 representative because I do not want other researchers to be subjected to the same unlawful policies and
15 actions that I have experienced. I have never served as a class representative in any prior action.

16
17 I declare under penalty of perjury that the foregoing is true and correct, and that this declaration
18 was executed at Ann Arbor, Michigan this 22nd day of September 2026.

19
20
21 

22 Katie Edwards
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Exhibit 1



Katie Edwards <edkatie@umich.edu>

1R21HD122186-01

Gilbert, Leah (NIH/NICHD) [E] <leah.gilbert@nih.gov>

Mon, Aug 10, 2026 at 11:36 AM

To: "edkatie@umich.edu" <edkatie@umich.edu>

Cc: "orosp-triage@umich.edu" <orosp-triage@umich.edu>, "NICHD HD eRA Notifications (NIH/NICHD)" <hderanotifications@mail.nih.gov>, "Fritz, Kelly (NIH/NICHD) [E]" <kelly.fritz@nih.gov>

Dear Dr. Dr. Edwards,

I am the Program Official assigned to your grant R21HD122186-01, and I am completing a review of your application. The purpose of this email is to resolve any administrative issues that may delay the release of a Notice of Award should we be able fund your application pending final NICHD leadership and budgetary review. Please review and address the following items at your earliest convenience.

1. There are some issues in your Data Management and Sharing Plan (DMSP) that need to be addressed to be in compliance with NIH Policy...Please revise your DMSP and then have the Authorized Organization Representative submit it through the "Data Management and Sharing Plan (DMSP) Revision" section of the Just in Time (JIT) Screen in eRA Commons.
 1. While we understand data sharing is determined by the Tribe from which the data originated, for a secondary analysis project however, we do encourage the PI to describe when, where, and how the documentation and/or code for processing and analyzing the data will be shared (e.g., a generalist repository, GitHub).
2. Please submit all Just in Time materials including investigator statements of support ensuring no scientific or budgetary overlap
3. To ensure alignment with Administration priorities, please adjust the term gender in the abstract and specific aims when referring to biological sex. Use the attached word document template for the edits, and have your AOR submit the edits via email, back to me.

Leah Gilbert, MD, MSPH, FACEP

Medical Officer, Pediatric Trauma and Critical Illness Branch

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

Office Phone: 301-594-3154

Email: leah.gilbert@nih.gov



RAA_Template (3).docx

13K

Exhibit 2

Modified Project Summary/Abstract Section

Enter the text here that is the new abstract information for your application.

Modified Specific Aims Section

Enter the text here that is the new specific aims information for your application.

Modified Public Health Relevance Section

Enter the text here that is the new public health relevance information for your application. Using no more than two or three sentences, describe the relevance of this research to public health.

Exhibit 3



Recipient Information	Federal Award Information
1. Recipient Name REGENTS OF THE UNIVERSITY OF MICHIGAN 1109 GEDDES AVE STE 3300 ANN ARBOR, MI 48109	11. Award Number 1R21HD122186-01
2. Congressional District of Recipient 06	12. Unique Federal Award Identification Number (FAIN) R21HD122186
3. Payment System Identifier (ID) 1386006309A1	13. Statutory Authority 42 USC 241 42 CFR 52
4. Employer Identification Number (EIN) 386006309	14. Federal Award Project Title Evaluation of a Sexual Violence Program for Youth Living on or Near a Rural Indian Reservation in the Northern Great Plains
5. Data Universal Numbering System (DUNS) 073133571	15. Assistance Listing Number 93.865
6. Recipient's Unique Entity Identifier GNJ7BBP73WE9	16. Assistance Listing Program Title Child Health and Human Development Extramural Research
7. Project Director or Principal Investigator Katie M Edwards, PHD Professor edkatie@umich.edu 734-763-2345	17. Award Action Type New Competing
8. Authorized Official Shandra White	18. Is the Award R&D? Yes
Federal Agency Information	Summary Federal Award Financial Information
9. Awarding Agency Contact Information Kelly Fritz EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT kelly.fritz@nih.gov 301-827-5429	19. Budget Period Start Date 09/03/2026 – End Date 08/31/2028
10. Program Official Contact Information LEAH KAYE Gilbert Program Officer EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT leah.gilbert@nih.gov (301) 594-3154	20. Total Amount of Federal Funds Obligated by this Action \$429,000 20 a. Direct Cost Amount \$275,000 20 b. Indirect Cost Amount \$154,000 21. Authorized Carryover 22. Offset 23. Total Amount of Federal Funds Obligated this budget period \$429,000 24. Total Approved Cost Sharing or Matching, where applicable \$0 25. Total Federal and Non-Federal Approved this Budget Period \$429,000 26. Project Period Start Date 09/03/2026 – End Date 08/31/2028 27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period \$429,000
	28. Authorized Treatment of Program Income Additional Costs
	29. Grants Management Officer - Signature Kelly Fritz

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.



EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R21HD122186-01

Principal Investigator(s):

Katie M Edwards, PHD

Award e-mailed to: swhite-gov@umich.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$429,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the University of Michigan 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 R21HD122186. 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,

Kelly Fritz
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)

Federal Direct Costs	\$275,000
Federal F&A Costs	\$154,000
Approved Budget	\$429,000
Total Amount of Federal Funds Authorized (Federal Share)	\$429,000
TOTAL FEDERAL AWARD AMOUNT	\$429,000
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$429,000

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$429,000	\$429,000

Fiscal Information:

Payment System Identifier: 1386006309A1
Document Number: RHD122186A
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026
HD	8014702	\$429,000

NIH Administrative Data:

PCC: PTCIB-LG / **OC:** 41021 / **Released:** 09/18/2026

Award Processed: 09/20/2026 12:06:30 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R21HD122186-01

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 – 1R21HD122186-01

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:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 2 CFR Part 200.
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 2 CFR Part 200. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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.

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R21HD122186. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Through acceptance of this award, recipient, and through implementation of this provision by recipient to each recipient investigator conducting work under this award, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this award, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy.

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 2 CFR Part 200, 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 that is found in [SAM.gov](https://sam.gov). Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities

For NIH awards that involve substance abuse, recipients are prohibited from using Federal funds, directly or indirectly, including through cost sharing, matching funds, or subsequent reimbursement, to support so-called "harm reduction" or "safe consumption" efforts that facilitate illegal drug use. Grant funds may not be used to purchase, distribute, or support drug paraphernalia as defined by law. This includes, but is not limited to, syringes or needles for illicit drug injection; pipes or supplies for safer smoking kits; fentanyl test strips or any other substance test kits, including xylazine and medetomidine test strips*; distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed here; purchase or distribute any other drug paraphernalia or supplies that promote or facilitate drug use not listed as acceptable. See [Updated Funding Guidance for Recipients on Supplies and Services](#).

Funds also may not support overdose hotlines whose primary purpose is to enable drug use by providing real-time virtual or phone-based accompaniment. These restrictions do not prohibit funding for legally permissible, evidence-based activities, such as the distribution of life-saving overdose prevention and response services, including purchase/distribution of naloxone or nalmeferne and/or other infectious disease prevention services.

Failure to comply with the programmatic requirements outlined in the link above, (which provides updated guidance for recipients on the supplies and services previously defined under harm reduction that can be supported with NIH funding), may result in enforcement actions consistent with the [NIH Grants Policy Statement - 8/8.5.2, 2 CFR 200.339](#) and [2 CFR 200.340](#), and the terms and conditions of this award.

*This prohibition does not apply to law enforcement, emergency medical services, public health officials, or healthcare professionals using drug testing technologies in the regular course of discharging their professional duties, or as specifically authorized by the program statute. Also, this prohibition does not apply to the following awards: Training Grants, Fellowship Awards, Construction and Modernization Awards, Instrumentation Awards, Small Business Innovation Research/Small Business Technology Transfer Awards.

Treatment of Program Income:

Additional Costs

Termination. This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities in line with 2 CFR 200.340(a)(4).

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R21HD122186-01

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.

Special Term and Condition

The recipient has revised the **Abstract, Public Health Relevance Statement, and Specific Aims** to ensure alignment with current agency priorities in **Training future biomedical scientists and/or Promoting research focused on scientifically valid, measurable health outcomes**. The project must be carried out in accordance with the revised **plan/section** submitted on **9/14**, which reflects the agreed upon updates. In accordance with this renegotiation, NIH funds may only be used to support activities within the revised scope of the award as described in the documents dated **DATE**. NIH funds may not be used to support activities that are not consistent with the revised scope of the award.

Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the **application** dated **6/13/2025**.

This is a Modular Grant Award without direct categorical cost breakdowns issued in accordance with the guidelines published in the [NIH Grants Policy Statement](#) (rev. 3/26). Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

This award is being issued as a multi-year funded (MYF) project, which provides all funding in a single budget period instead of annual, incremental awards. Due to the use of the MYF funding model, this award will be affected by the Federal funds expiration policy. Per [Section 5.3](#) of the NIH Grants Policy Statement (rev. 3/26), "All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability." Based on this restriction, all funds issued for this award must be obligated by **June 30, 2031**.

NOTE: No Cost Extension (NCE) requests at the end of the original project period require written NIH prior approval. Such requests must be submitted prior to the project period end date.

Data Management and Sharing Policy: Applicable

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

Budget	Year 1
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DMS Costs	\$0
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SPREADSHEET SUMMARY**AWARD NUMBER:** 1R21HD122186-01**INSTITUTION:** The Regents of the University of Michigan

Budget	Year 1
TOTAL FEDERAL DC	\$275,000
TOTAL FEDERAL F&A	\$154,000
TOTAL COST	\$429,000

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	56%
F&A Cost Base 1	\$275,000
F&A Costs 1	\$154,000