EXHIBIT 20

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF KATIE EDWARDS

I, Katie Edwards, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am a Professor of Social Work at the University of Michigan. My research focuses on preventing sexual and related forms of violence among minority communities by using evidence-based, affirming, and culturally-grounded approaches. My current work is focused on program development and evaluation with Indigenous youth and communities, as well as LGBTQ+ youth. In 2024, I was named by Stanford University as one of the top two percent researchers in the world, and 26th out of 12,726 researchers in the field of criminology. In my lab, we have some of the first studies ever to show we have reduced violence and alcohol use among LGBTQ+ youth as well as sexual violence among Indigenous youth.
2. I am offering this declaration in my individual capacity and not on behalf of my employer.
3. My interest in this area of work began during my undergraduate studies. Through my studies and volunteer work, I saw the damaging effects of sexual violence and other forms of violence, and I wanted to learn how to prevent violence from happening in the first place. While most of my work in graduate school focused on college students, early on in my career as an assistant professor, I realized that most of the scientific literature at the time did not address the particular needs of LGBTQ+ youth, a glaring gap especially given that this demographic experiences disproportionately higher rates of sexual and other forms of

violence. My passion grew from wanting to work to help all youth who were experiencing these harms and especially youth experiencing high rates of violence about whom we as a field had done relatively less research.

4. Before working at the University of Michigan, I was a Professor of Educational Psychology at the University of Nebraska-Lincoln. Before that, I was an Assistant and Associate Professor of Psychology at the University of New Hampshire.
5. I received my B.S. in Psychology in 2005 from the University of Georgia. I completed my Ph.D. in Clinical Psychology at Ohio University in 2011, and I received a graduate certificate in Women and Gender Studies from Ohio University that same year.
6. To date, I have published more than 220 peer-reviewed journal articles, which were made possible, in part, through obtaining more than $23 million in research funding over the course of my career.
7. I have applied for and received 10 grants from the NIH over the course of my career. The application process for each grant was a lengthy and involved one, but that process—at least until recently—helped ensure that the most rigorous and impactful research is conducted. In my experience, preparing an application requires months, if not years, of work—from pilot studies, literature review or other background research, to input from community partners and fellow researchers, to honing methodological design—and often new studies will build off of the work and findings from previous studies.
8. Since March 2025, NIH has terminated at least six grants that fund research projects for which I am the principal investigator or co-investigator. For each of these grants, NIH stated in a termination notice that the project "no longer effectuates agency priorities." The total amount awarded originally across those six grants is approximately $11.9 million.
9. One of those terminated grants is a project-based R01 grant that was awarded on July 22, 2022. A true and correct copy of the notice of award (NOA) for that grant is attached hereto as Exhibit A. That grant—titled *An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes among Sexual and Gender Minority Men* (Project Number 5R01MD016384)—originally had a total award value of over $3.8 million. *See id.*
10. Sexual assault happens more often to sexual minority men than to heterosexual men, but the scientific community has a limited understanding of why that disparity exists—and of how to

prevent sexual assault and support those who have experienced it among this community. The goal of this project was to use a rigorous methodology to focus on factors that predict sexual assault experiences among sexual minority men and trans-masculine people, as well as their recovery in the aftermath of those experiences. And more specifically, our goal was to use findings from this study to better understand how to reduce the risk of sexual violence experiences among sexual minority men and its negative outcomes, with the longer-term goal of developing programs and policies to address this public health crisis. Filling this gap in the literature and in public health is important because, among other reasons, an estimated 9.3% of the population identifies as LGBTQ+ (and more when looking at young people specifically), and because sexual violence is quite costly on society, with the Centers for Disease Control and Prevention (CDC) estimating that the lifetime cost of rape as $122,461 per survivor (a figure that includes medical care, lost productivity from work, and criminal justice costs). A true and correct copy of a screen capture of the CDC's website providing that estimated cost, last accessed April 24, 2025, is attached hereto as Exhibit B.

11. This project took the form of a survey administered over a two-year span. Each participant was supposed to take a baseline survey followed by a survey every six months (*i.e.*, a survey at six, 12, 18, and 24 months after the baseline survey). The survey at each time point asked largely the same questions, which sought information from the participants about experience with, among other things, sexual assault, alcohol consumption, discrimination, and mental health. While the baseline survey asked for information about a participant's entire past, each follow-up survey asked the participant for information that pertained to the six months since their prior survey. Each survey featured hundreds of questions and took participants on average 45 minutes to an hour to complete. Our hope was that analysis of the data collected across this two-year span and from 3,107 participants would ultimately provide guidance on interventions to prevent and respond to sexual violence among sexual minority men (many of whom were also racial/ethnic minorities) ultimately reducing health disparities and reducing high costs of sexual violence in the U.S.
12. I aligned this project with NIMHD's goals to advance the scientific understanding of health disparities and improve minority health.
13. A lot of time and effort went into the application for this project. My colleagues and I spent months immersing ourselves in the scientific literature, reading previously published

empirical and theoretical literature and drafting literature reviews on the subject matter—and ultimately coming to appreciate how little research existed at the time that was focused on how sexual violence specifically affects sexually minority men (especially for those identified as people of color). After reading and summarizing existing literature directly and indirectly related to sexual assault experiences among sexual minority men, we turned towards proposing a new theoretical model to understand why sexual violence happens among this population—a process that also took several months. The goal of that model was to make sense of the limited data already available, and to hypothesize what factors could affect the rate at which sexual minority men experience sexual assault as well as factors impacting their recovery. We developed ways to test this model and, after receiving feedback from colleagues, we drafted and submitted an application for funding to the NIMHD.

14. The application was referred to a study section group within NIH that consisted of a number of peer reviewers, including three peer reviewers specifically assigned to this application. That group provided feedback, but the NIMHD did not approve any award of funding, and we spent several months after that working on revising the application materials in light of and responding to that feedback. Those revisions included providing more information to support the proposed theoretical model, refining our methodology for collecting and analyzing data, and addressing a human subjects safety concern regarding data de-identification. We then resubmitted our application, which was again referred to a study section group of expert reviewers, three of whom were assigned to provide an in-depth and critical review of our grant. Following peer review that resulted in a fundable score, the NIMHD requested that we respond to a few remaining/minor matters, and we submitted a brief memo to address those remaining matters. Afterwards, our project was recommended for funding, and the notice of award was issued.
15. Since approving funding for this project, NIH has renewed this grant three times. NIH officials never raised any concerns with this grant during those renewal reviews.
16. There has been much progress in this study since NIH approved it. We have completed enrollment for the study, recruiting over 3,100 participants. Although the start date varies across participants, most participants are somewhere between their 18-month and 24-month

follow-up survey, with about 14% of individuals who have completed the entire span of the study. Data collection was set to wrap up in about a year.

17. Staff who work on this project were funded, at least in part, by this grant. For example, this grant pays a portion of my salary. A project coordinator for this project is fully funded by this project, and a project manager, a postdoctoral student, and part-time research assistants are partially funded by this project as well.
18. On March 11, 2025, an NIH official wrote me an email stating that "we're still working on it, ironing out things on our end," referring to a renewal and transfer of this grant.
19. But on March 12, 2025, NIH issued a notice terminating this grant. A true and correct copy of this termination notice is attached hereto as Exhibit C. Prior to this notice, there was never any indication that this grant was in jeopardy.
20. The termination notice does not include any individualized explanation for why the grant was cancelled and fails to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

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

Ex. C at 1.

21. On March 20, 2025, NIH issued a revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.
22. I do not understand what the notice or revised NOA means by the phrase "based on gender identity," and I do not understand why NIH believes this project is "based on gender identity." I also am uncertain why NIH believes this project does not effectuate agency priorities. I also do not know what the notice means by the term "biological realities."

23. This termination will severely hinder and may well completely preclude our ability to draw conclusions and develop recommendations from this study. As noted, most of the participants have yet to complete the entire course of the study. Although we are still conducting surveys for a limited time thanks to alternative funding sources, those sources are limited, and they will not last long enough to allow us to collect a full set of surveys for most—let alone all—of the 3,107 participants in this study. If, as forecasted, most participants do not have the opportunity to complete the final survey (or surveys for some participants), this will reduce the amount of data we can analyze including consistency of administrations across participants (a methodological flaw) in addition to limiting the statistical power of the analyses we are able to run. Collectively, these methodological and statistical issues will prohibit our ability to draw conclusions from the data we have collected and restrict the possible recommendations that can be developed to benefit sexual minority men (including racial/ethnic sexual minority men) across the U.S. That reduced ability to draw statistical inferences means that this area of research—and the populations served by this area of research—will not be able to benefit nearly as much as they would have, had funding for this project not been terminated. And this all assumes we even have someone to analyze the data we have collected: without sufficient additional funding, which at this time I do not anticipate securing, we will not have money to pay for an individual with the pertinent statistical background and expertise to analyze data. The funds for the statistician and her team to conduct rigorous study analyses were all terminated. That task alone requires months of data cleaning and weeks of running and refining complex statistical models.
24. Another grant that supports my research that the NIH terminated is a three-year project-based R34 grant originally awarded on October 12, 2023 by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). A true and correct copy of the NOA for that grant is attached hereto as Exhibit E. The total amount originally approved for this grant—titled *An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth* (Project Number R34AA030662)—was $653,281. *See* Ex. E.
25. Based on work and findings by a prior NIH-funded project, my colleagues and I found that online intervention for LGBTQ+ youth reduced teen dating violence and alcohol use. From there, we thought it would be beneficial to better understand and develop programming that

would help not only LGBTQ+ youth but also their caregivers, as research shows that having a supportive caregiver also benefits LGBTQ+ youth tremendously. More broadly, the project also aims to facilitate family bonding and communications in addition to caregiver support and affirmation.

26. This project took the form of an online program with two groups: an experimental group and a control group. Participants in the experimental group would participate in a weekly online group intervention session for seven weeks, with separate programming for the participants who were sexual and gender minority youth (aged 15 to 18) and for their respective caregivers. Programming for caregivers focuses on increasing parental knowledge, acceptance, and support for their sexual and gender minority youth, as well as providing caregivers with evidence-based strategies focused on reducing risky behaviors among teens. Programming for sexual and gender minority youth focuses on reducing internalized stigma; enhancing social-emotional skills; increasing accurate perceptions of alcohol and dating violence norms; and increasing alcohol refusal skills. During the seven-week period that participants in the experimental group would take part in these sessions, individuals in the control group would receive periodic check ins but no similar programming. Before and after the seven-week period, we would conduct a survey for both the youth and their caregivers across both the experimental and control groups, to measure outcomes like frequency of dating violence and alcohol use and perceptions of trust or affirmation in the caregiving relationship.
27. In line with our understanding of our ethical obligations to all participants, at the completion of the seven-week period, we then offered all participants in the control group the opportunity to participate in the same programming in which the experimental group participants took part. But because there would be no comparable control group for these individuals during this subsequent seven-week period, no data would (or could) be meaningfully used from this intervention during that period to inform our understanding of how it worked.
28. My Co-Principal Investigators and I aligned this project with the goals of NIAAA to prevent alcohol abuse and related risk behaviors (such as dating violence) among diverse populations of youth.

29. As with the R01 grant described above, my colleagues and I spent months reviewing literature to prepare this application. Also, over the course of several months, we had to think very carefully about what a program for caregivers would look like, how to integrate that component, and how to go about this integration safely given the particular vulnerability of sexual and gender minority youth. Once we submitted the application, the level of rigor in the review process for this grant was similar to that of the R01 grant described above: our application was submitted to a study group, we did not initially receive funding and instead received feedback from the group, we worked for months refining the application, and after we re-submitted our grant application (along with a follow-up brief memo on any remaining issues flagged by the reviewers), NIH approved our grant.
30. NIH disbursed the total amount for this grant in its first disbursement. Still, we were required to submit annual progress reports. We have submitted one annual report, and the grant was renewed with no issues.
31. Staff who work on this project were funded, at least in part, by this grant. For example, this grant pays a portion of my salary, the salary of another PI, and the salary of a co-investigator. A project coordinator for this project is fully funded by this project, a graduate student, and part-time research assistants/program facilitators are partially funded by this project as well.
32. There had been a lot of progress on this study so far. We had designed the intervention program, conducted a pilot with one cohort of families, and started up the randomized control trial portion of the study. Our goal was to enroll around 80 families through the study, and we had already begun programming for the first cohort of participants—approximately 22 families (half in the experimental group, half in the control group). The rest of the participants would have participated in future cohorts.
33. But on March 21, 2025, NIH issued a notice stating that this grant was terminated. A true and correct copy of this termination notice is attached hereto as Exhibit F. Prior to this notice, there was never prior indication during the renewal process that this grant was in jeopardy.
34. The termination notice does not include any individualized explanation for why the grant was cancelled, and fails to discuss any of the data or analysis from our application, the annual progress report, or other related material. Instead, the notice includes the following language about its decision:

> 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.

Ex. F at 1.

35. On March 25, 2025, NIH issued a revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit G.

36. As with the termination notice for the R01 grant described above, I do not understand what the notice or revised NOA means by the phrase "based on gender identity," and I do not understand why NIH believes this project is "based on gender identity." I also do not understand why NIH believes this project does not effectuate agency priorities. I also do not know what the notice means by the term "biological realities."

37. This termination will hinder our ability to draw conclusions and develop recommendations from this study. As discussed, at the time the grant was terminated, we were in the middle of program interventions for the first cohort of participants. But because of this termination, we lacked the funding to ensure that we could complete the entirety of this cohort consistent with our ethical obligations to our participants—that is, the full seven weeks for *both* the experimental group and the control group, followed by seven weeks of intervention for those in the control group. As such, to abide by our ethical obligations, we were forced to prematurely begin interventions for the control group midway through the initial seven-week period. To draw meaningful conclusions from this study, the control group should have received the intervention after their final surveys. But because the termination forced us to prematurely begin the intervention for the control group, we can no longer use any of the data from this cohort for our analyses—at least not as intended with a comparison group. We also will not have statistical power to conduct analyses given that our sample size will fall short of what was proposed/intended. And at this time, we do not anticipate being able to secure sufficient additional funding to allow us to resume this study for future cohorts.

38. Since February 2025, NIH issued substantially similar termination notices or revised NOAs for four other grants that support my work, with the assertion that each "award no longer

effectuates agency priorities." Those projects are: 5R21MD018509 (*Development and Pilot Evaluation of an Online Mentoring Program to Prevent Adversities Among Trans and Other Gender Minority Youth*); 5R01AA031213 (*The Impact of Minority Stress on Alcohol-Related Sexual Assault Among Sexual Minority College Students: An Intersectional, Mixed-Methodological Study*); 5R01MD017573 (*Sexual Assault Recovery Among Sexual Minority Women: A Longitudinal, Multi-Level Study*); and R15 AA030898 (*Reconstruction of an SGM-specific Sexual Violence Peer Support Program [SSS+]*).

39. Every study is unique, and so the preparation of grant application materials will necessarily be unique, but the scale of the time, effort, labor, outreach, and scientific rigor was generally similar across all those grant applications. And yet, each of these termination notices failed to offer any individualized explanation of why the grant was cancelled and failed to discuss any of the data or analysis from our application, any annual progress report, or other related material. And because of the vague terms used across these termination notices, I am uncertain why the projects no longer effectuate agency priorities, how I can revise these projects to align with agency priorities, and how I can align future grant applications with these priorities.
40. Because of these terminations, projects and studies will be negatively impacted. My co-investigators and I will have an impaired—and in some cases, foreclosed—ability to complete studies, analyze any data collected, draw meaningful conclusions from that data, and develop recommendations to address health disparities experienced by vulnerable subpopulations—including sexual and gender minority individuals, LGBTQ+ youth, and people of color.
41. These terminations have and will continue to negatively impact our staff. For example, several staff have already been terminated, and more terminations are soon to happen because of a lack of funding resulting from the termination of these grants. These terminated grants funded part of my salary as well as the salary of other investigators on these grants. And much of our staff—from project coordinators and managers to graduate students to postdoctoral fellows to research assistants—were funded in large part through these grants. Absent additional funding, most if not all of those individuals will have severely reduced hours or will be completely terminated, and some are already terminated. For example, a postdoctoral fellow on these projects will now have their fellowship terminated in June. And

although my co-investigators and I are scrambling to secure replacement funding, that endeavor is taking away time from our current research, and I do not anticipate being able to secure nearly enough to secure the amount of funding (millions of dollars) that we would have had with those terminated grants.

42. On a personal level, I have never been more stressed in my entire life than I am now because of the impacts of these terminations. That stress has taken an emotional and physical toll, as the harms that have already resulted and will result from these cuts—to our staff, to our study participants, to the populations served by this research—have weighed on me each day. I regularly spend 15 or more hours a day trying to address the fallout from these terminations, from working on plans to ethically wind down studies; supporting staff and students who are distraught over losing work they are deeply passionate about and who are likely losing their jobs; and submitting to date over 20 grants/letters requesting funding to donors and nonprofit organizations (with no funding having been obtained to date). But I don't see how else to fund these programs besides through the now-terminated NIH grants.
43. Prior to March 2025, NIH had never terminated a grant that supported my research.
44. Appeals for three of the grants that support my research have been submitted. I anticipate that appeals for at least one of the other terminated grants will be submitted.
45. I supported submitting an appeal for each of these grants in large part because I do not anticipate being able to find replacement funding for the projects that fund them. But I still have no idea why the grants that support my research were terminated, and I had no idea how to address any agency concerns or recharacterize or revise my project for the purposes of appeal.
46. I also do not know whether the appeal has any chance of success, given the following language across the termination notices I received: "The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

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

Executed this 24th day of April, 2025.

Katie Edwards

EXHIBIT A

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

Notice of Award
FAIN# R01MD016384
Federal Award Date
07-22-2022

Recipient Information

1. Recipient Name
BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA
2200 VINE ST BOX 830861

LINCOLN, 68503

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1470049123A8

4. Employer Identification Number (EIN)
470049123

5. Data Universal Numbering System (DUNS)
555456995

6. Recipient's Unique Entity Identifier
HTQ6K6NJFHA6

7. Project Director or Principal Investigator
Katie M Edwards, PHD
Associate Professor
katie.edwards@unl.edu
603-422-3207

8. Authorized Official
Craig Goodrich

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

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

10. Program Official Contact Information
ARIELLE SAMANTHA Gillman
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
arielle.gillman@nih.gov
301-402-1366

Federal Award Information

11. Award Number
1R01MD016384-01A1

12. Unique Federal Award Identification Number (FAIN)
R01MD016384

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men

15. Assistance Listing Number
93.307

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

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07-22-2022 **– End Date** 03-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$801,820
20 a. Direct Cost Amount	$526,925
20 b. Indirect Cost Amount	$274,895
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$801,820
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$801,820
26. Project Period Start Date 07-22-2022 **– End Date** 03-31-2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$801,820

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

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

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 1R01MD016384-01A1

Principal Investigator(s):
Katie M Edwards, PHD

Award e-mailed to: unlosp@unl.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $801,820 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEBRASKA LINCOLN in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD016384. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	$119,981
Fringe Benefits	$44,571
Personnel Costs (Subtotal)	$164,552
Consultant Services	$7,500
Materials & Supplies	$3,500
Travel	$1,585
Other	$268,170
Subawards/Consortium/Contractual Costs	$81,618
Federal Direct Costs	$526,925
Federal F&A Costs	$274,895
Approved Budget	$801,820
Total Amount of Federal Funds Authorized (Federal Share)	$801,820
TOTAL FEDERAL AWARD AMOUNT	$801,820
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$801,820

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$801,820	$801,820
2	$771,707	$771,707
3	$767,135	$767,135
4	$757,033	$757,033
5	$753,439	$753,439

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

Fiscal Information:

Payment System Identifier: 1470049123A8
Document Number: RMD016384A
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022	2023	2024	2025	2026
MD	8472687	$801,820	$771,707	$767,135	$757,033	$753,439

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

NIH Administrative Data:
PCC: IBB03 / **OC**: 41021 / **Released**: Grant, Priscilla 07-15-2022
Award Processed: 07/22/2022 12:21:32 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MD016384-01A1

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MD016384-01A1

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

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

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

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01MD016384. 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 – MD SPECIFIC AWARD CONDITIONS – 1R01MD016384-01A1

Clinical Trial Indicator: No

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

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

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

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

INFORMATION The Initial Review Group has made the following budget recommendations: The committee noted the proposed resources to support the recruitment of the planned sample size was inadequate.

INFORMATION: In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with an 8.3-month budget period and with 12 months of support. Continuation awards will cycle each year on April 1st.

INFORMATION: Although the budget period start date for this award is July 22nd, this award includes funds for 12 months of support. Future year budget periods will cycle on April 1st. Allowable pre-award costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, and with institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

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

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01MD016384-01A1

INSTITUTION: UNIVERSITY OF NEBRASKA LINCOLN

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$119,981	$117,517	$115,053	$115,053	$90,053
Fringe Benefits	$44,571	$43,339	$42,107	$42,107	$32,107
Personnel Costs (Subtotal)	$164,552	$160,856	$157,160	$157,160	$122,160
Consultant Services	$7,500	$3,125	$3,125	$3,125	$7,500
Materials & Supplies	$3,500	$1,000	$1,000	$1,000	$1,000
Travel	$1,585	$1,585	$1,585	$1,585	$1,585
Other	$268,170	$280,580	$281,336	$259,964	$288,278
Subawards/Consortium/Contractual Costs	$81,618	$76,395	$76,395	$99,526	$99,526
TOTAL FEDERAL DC	$526,925	$523,541	$520,601	$522,360	$520,049
TOTAL FEDERAL F&A	$274,895	$248,166	$246,534	$234,673	$233,390
TOTAL COST	$801,820	$771,707	$767,135	$757,033	$753,439

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	$495,307	$447,146	$444,206	$422,834	$420,523
F&A Costs 1	$274,895	$248,166	$246,534	$234,673	$233,390

EXHIBIT B

Sexual Violence Prevention

JANUARY 23, 2024

About Sexual Violence

KEY POINTS

- Sexual violence is a significant problem in the United States.
- Sexual violence has a profound impact on lifelong health, opportunity, and well-being.

What is sexual violence?

Sexual violence is sexual activity when consent is not obtained or freely given. It impacts every community and affects both sexes and people of all sexual orientations and ages. Anyone can experience or perpetrate sexual violence.

The perpetrator of sexual violence is usually someone the survivor knows. This can include a friend, current or former intimate partner, coworker, neighbor, or family member. Sexual violence can occur in person, online, or through technology. This includes posting or sharing sexual pictures of someone without their consent, or non-consensual sexting.

Did you know?

Child sexual abuse is a form of sexual violence. Read more information about child sexual abuse.

What is sexual violence?

Quick facts and stats

Researchers know the numbers underestimate this problem because many cases are unreported. Survivors may be ashamed, embarrassed, or afraid to tell the police, friends, or family about the violence. Victims may also keep quiet because they have been threatened or do not think anyone will help them.

Sexual violence is common:

- Over half of women and almost one in three men have experienced sexual violence involving physical contact during their lifetimes. [1]
- One in four women and about one in 26 men have experienced completed or attempted rape. [1]
- About one in nine men were made to penetrate someone during his lifetime. [1]
- One in three women and about one in nine men experienced sexual harassment in a public place. [1]

Sexual violence starts early:

- More than four in five female rape survivors reported that they were first raped before age 25 and almost half were first raped as a minor (i.e., before age 18). [1]
- Nearly eight in 10 male rape survivors reported they were made to penetrate someone before age 25 and about four in 10 were first made to penetrate as a minor. [1]

Some groups are affected more than others. Women and racial and ethnic minority groups experience a higher burden of sexual violence. [1] [2] [3] [4] [5] For example, more than two in five non-Hispanic American Indian or Alaska Native and non-Hispanic multiracial women were raped in their lifetime. [1]

Sexual violence is also costly. Recent estimates put the lifetime cost of rape at $122,461 per survivor, including medical care, lost productivity from work, and criminal justice costs. [6]

Outcomes

Some consequences are physical, like bruising and genital injuries, sexually transmitted infections, and pregnancy (for women). Some consequences are psychological, such as depression, anxiety, and suicidal thoughts. [7]

The consequences may be chronic. Survivors may suffer from post-traumatic stress disorder and experience recurring reproductive, gastrointestinal, cardiovascular, and sexual health problems. [7]

Sexual violence is also linked to negative health behaviors. Sexual violence survivors are more likely to smoke, abuse alcohol, use drugs, and engage in risky sexual activity. [8]

The trauma from sexual violence may impact a survivor's employment. This refers to time off from work, diminished performance, job loss, or inability to work. These issues disrupt earning power and have a long-term effect on the economic well-being of survivors and their families. Coping and completing everyday tasks after victimization can be challenging. Survivors may have difficulty maintaining personal relationships, returning to work or school, and regaining a sense of normalcy. [7]

Sexual violence is also connected to other forms of violence. For example, girls who have been sexually abused are more likely to experience additional sexual violence. They are also more likely to become victims of intimate partner violence in adulthood. Bullying perpetration in early middle school is linked to sexual harassment perpetration in high school. [9]

Prevention

Sexual violence can be prevented. Certain factors my increase or decrease the risk of perpetrating or experiencing sexual violence.

Preventing sexual violence requires understanding and addressing the factors that put people at risk for or protect them from violence. We must also understand how historical trauma and structural inequalities impact health. [1]

Changing social norms, teaching skills, empowering girls and women, and creating protective environments can help prevent and reduce sexual violence. We all have a role to play in prevention.

Need help? Know someone who does?

Rape, Abuse and Incest National Network's (RAINN) National Sexual Assault Hotline

Call **800.656.HOPE (4673)** to be connected with a trained staff member from a sexual assault service provider in your area.

SOURCES

CONTENT SOURCE:
National Center for Injury Prevention and Control

REFERENCES

1. Basile KC, Smith SG, Kresnow M, Khatiwada S, & Leemis RW. (2022). The National Intimate Partner and Sexual Violence Survey: 2016/2017 Report on Sexual Violence. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.
2. Basile KC, Breiding MJ, Smith SG. (2016). Disability and risk of recent sexual violence in the United States. American journal of public health, 106(5):928-33
3. Thurston, A. M., Stöckl, H., & Ranganathan, M. (2021). Natural hazards, disasters and violence against women and girls: A global mixed-methods systematic review. BMJ Global Health, 6(4), e004377. https://www.doi.org/10.1136/bmjgh-2020-004377
4. National Sexual Violence Resource Center. (2021) Sexual Violence in Disasters. https://www.nsvrc.org/sites/default/files/2021-11/sexual_violence_in_disasters_final508_0.pdf PDF
5. Deering, K. N., Amin, A., Shoveller, J., Nesbitt, A., Garcia-Moreno, C., Duff, P., ... & Shannon, K. (2014). A systematic review of the correlates of violence against sex workers. American journal of public health, 104(5), e42-e54.
6. Peterson C, DeGue S, Florence C, Lokey C. (2017). Lifetime Economic Burden of Rape in the United States. American Journal of Preventive Medicine 52(6): 691-701.

7. Basile KC and Smith SG. (2011). Sexual Violence Victimization of Women: Prevalence, Characteristics, and the Role of Public Health and Prevention. American Journal of Lifestyle Medicine (5): 407-417.
8. Basile KC, Clayton HB, Rostad WL, & Leemis RW. (2020). Sexual violence victimization of youth and health risk behaviors. American Journal of Preventive Medicine, 58(4), 570-579.
9. Espelage DL, Basile KC, Hamburger ME. (2012). Bullying perpetration and subsequent sexual violence perpetration among middle school students. Journal of Adolescent Health 50(1): 60-65.

EXHIBIT C

March 12, 2025

Craig Goodrich
University of Nebraska Lincoln
Email: cgoodrich3@unl.edu

Dear Craig Goodrich:

Funding for Project Number is 5 R01 MD016384-03 hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,1 and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.2

The 2024 Policy Statement applies to your project because NIH approved your grant on August 22, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

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

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5 R01 MD 016384-03 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

---

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

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

Administrative Appeal

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

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

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

Sincerely,

Michelle G. Bulls, on behalf Priscilla Grant Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Administration
Office of Extramural Research

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

EXHIBIT D

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

Notice of Award
FAIN# R01MD016384
Federal Award Date
03/20/2025

Recipient Information

1. Recipient Name
BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA
2200 VINE ST # 830861
LINCOLN, NE 68503

2. Congressional District of Recipient
01

3. Payment System Identifier (ID)
1470049123A8

4. Employer Identification Number (EIN)
470049123

5. Data Universal Numbering System (DUNS)
555456995

6. Recipient's Unique Entity Identifier
HTQ6K6NJFHA6

7. Project Director or Principal Investigator
Katie M Edwards, PHD
Associate Professor
katie.edwards@unl.edu
6034223207

8. Authorized Official
Craig Goodrich

Federal Agency Information

9. Awarding Agency Contact Information
Sy Shackleford

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

10. Program Official Contact Information
ARIELLE SAMANTHA Gillman
Program Officer
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES
arielle.gillman@nih.gov
301-402-1366

Federal Award Information

11. Award Number
5R01MD016384-03

12. Unique Federal Award Identification Number (FAIN)
R01MD016384

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Innovative, Prospective Model to Understand Risk and Protective Factors for Sexual Assault Experiences and Outcomes Among Sexual Minority Men

15. Assistance Listing Number
93.307

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

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

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 04/01/2024 **– End Date** 12/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$767,135
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$767,135
26. Project Period Start Date 07/22/2022 **– End Date** 12/31/2024	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,340,662

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Priscilla Grant

30. Remarks

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

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I – AWARD DATA – 5R01MD016384-03 REVISED

Principal Investigator(s):
Katie M Edwards, PHD

Award e-mailed to: unlospawards@unl.edu

Dear Authorized Official:

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

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD016384. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	$115,053
Fringe Benefits	$42,107
Personnel Costs (Subtotal)	$157,160
Consultant Services	$3,125
Materials & Supplies	$1,000
Travel	$1,585
Other	$281,336
Subawards/Consortium/Contractual Costs	$76,395
Federal Direct Costs	$520,601
Federal F&A Costs	$246,534
Approved Budget	$767,135
Total Amount of Federal Funds Authorized (Federal Share)	$767,135
TOTAL FEDERAL AWARD AMOUNT	$767,135
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$767,135	$767,135

Fiscal Information:
Payment System Identifier: 1470049123A8
Document Number: RMD016384A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
MD	8472687	$767,135

NIH Administrative Data:
PCC: IBB03AG / **OC**: 41025 / **Released**: 03/20/2025
Award Processed: 03/21/2025 12:06:15 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01MD016384-03 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 – 5R01MD016384-03 REVISED

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

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

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

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

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01MD016384. 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 – MD SPECIFIC AWARD CONDITIONS – 5R01MD016384-03 REVISED

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

INFORMATION: It is the policy of NIH not to prioritize research activities that focus on gender identity. This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Therefore, this project is terminated. The University of Nebraska Lincoln may request funds to support patient safety and orderly closeout of the project. Funds used to

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

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ISSUED ON 03/13/2025 ALSO APPLY TO THIS AWARD:

INFORMATION: In accordance with the relinquishing statement dated December 11th, 2024, this revised award terminates support for this project on December 31st, 2024.

It is the policy of NIH not to prioritize research activities that focus on gender identity. This project no longer effectuates agency priorities. Therefore, this project is terminated. The University of Nebraska Lincoln may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

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

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD ISSUED ON 06/21/2024 ALSO APPLY TO THIS AWARD:

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

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

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

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

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01MD016384-03 REVISED

INSTITUTION: UNIVERSITY OF NEBRASKA LINCOLN

Budget	Year 3
Salaries and Wages	$115,053
Fringe Benefits	$42,107
Personnel Costs (Subtotal)	$157,160
Consultant Services	$3,125
Materials & Supplies	$1,000
Travel	$1,585
Other	$281,336
Subawards/Consortium/Contractual Costs	$76,395
TOTAL FEDERAL DC	$520,601
TOTAL FEDERAL F&A	$246,534
TOTAL COST	$767,135

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	55.5%
F&A Cost Base 1	$444,206
F&A Costs 1	$246,534

EXHIBIT E

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Notice of Award
FAIN# R34AA030662
Federal Award Date
10/12/2023

Recipient Information

1. Recipient Name
THE REGENTS OF THE UNIVERSITY OF COLORADO
1420 AUSTIN BLUFFS PKWY
COLORADO SPRINGS, CO 80918

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1846000555E7

4. Employer Identification Number (EIN)
846000555

5. Data Universal Numbering System (DUNS)
186192829

6. Recipient's Unique Entity Identifier
RH87YDXC1AY5

7. Project Director or Principal Investigator
Heather Littleton, PHD (Contact)

hlittlet@uccs.edu
252-916-2976

8. Authorized Official
Gwendolyn A. Logan Gennaro

Federal Agency Information

9. Awarding Agency Contact Information
Donna Stringfield
Extramural Support Assistant
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
donna.stringfield@nih.gov
301-443-3851

10. Program Official Contact Information
TATIANA NIKOLAYEVNA Balachova

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
tatiana.balachova@nih.gov
301-443-5726

Federal Award Information

11. Award Number
1R34AA030662-01A1

12. Unique Federal Award Identification Number (FAIN)
R34AA030662

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth

15. Assistance Listing Number
93.273

16. Assistance Listing Program Title
Alcohol Research Programs

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/01/2023 **– End Date** 08/31/2026	
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	$653,281
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$653,281
26. Project Period Start Date 09/01/2023 **– End Date** 08/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$653,281

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Lauren Early

30. Remarks

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

Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

SECTION I – AWARD DATA – 1R34AA030662-01A1 REVISED

Principal Investigator(s):
Katie M Edwards, PHD
Heather Littleton (contact), PHD

Award e-mailed to: osp@uccs.edu

Dear Authorized Official:

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

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Alcohol Abuse And Alcoholism of the National Institutes of Health under Award Number R34AA030662. 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,

Lauren Early
Grants Management Officer
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Additional information follows

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

Salaries and Wages	$182,211
Fringe Benefits	$61,770
Personnel Costs (Subtotal)	$243,981
Consultant Services	$12,181
Travel	$3,852
Other	$77,005
Subawards/Consortium/Contractual Costs	$149,733
Federal Direct Costs	$486,752
Federal F&A Costs	$166,529
Approved Budget	$653,281
Total Amount of Federal Funds Authorized (Federal Share)	$653,281
TOTAL FEDERAL AWARD AMOUNT	$653,281
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$653,281	$653,281

Fiscal Information:

Payment System Identifier:	1846000555E7
Document Number:	RAA030662A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023
AA	8484370	$653,281

NIH Administrative Data:
PCC: AP TD / **OC**: 41021 / **Released**: Early, Lauren 10/11/2023
Award Processed: 10/12/2023 12:03:16 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34AA030662-01A1 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R34AA030662-01A1 REVISED

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

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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) R34AA030662. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A

final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

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

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

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

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

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by 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 – AA SPECIFIC AWARD CONDITIONS – 1R34AA030662-01A1 REVISED

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION:

Revised to 1) correct budget and project period end dates to 08/31/2026 and 2) add the following Multi-year funded term:

CHANGE TO A MULTI-YEAR FUNDED AWARD: Although the application upon which this grant is awarded was submitted as a three-year grant request, in order to meet NIAAA program priorities and objectives in Fiscal Year 2023, this grant has been converted to a **multi-year funded award**, with all years of funding provided in the current fiscal year. Special monitoring requirements specific to multi-year funded awards, including the progress report due on or before the anniversary of the budget/project period start date of the award, are detailed in Section III in this Notice of Award.

****

Based on a review of your application and the need to effect NIAAA budgetary and programmatic goals, your requested direct cost funding has been adjusted.

SALARY LIMITATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at https://grants.nih.gov/grants/policy/salcap_summary.htm.

PRIOR APPROVALS: In keeping with NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grant recipient institution must secure and retain the signatures of all PIs following their own internal processes.

CONSORTIA: This award includes funds awarded for consortium activity with **University of Nebraska-Lincoln**. Consortia are to be established and administered as described in the NIH Grants Policy Statement (see http://grants.nih.gov/grants/policy/policy.htm#gps).

HUMAN SUBJECTS--VULNERABLE POPULATIONS: The research supported by this award involves a population of human subjects identified as **"vulnerable"**. Investigators who conduct research involving vulnerable populations, including pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations (https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm).

INFORMATION: In accordance with the NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research, it is expected that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a Single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. This grant is expected to develop and participate in a collaborative, central, or shared IRB that will streamline IRB approval while maintaining appropriate human subjects protections. This award reflects the National Institute on Alcohol Abuse and Alcoholism's (NIAAA's) acceptance of the sIRB plan submitted in the competing application. (See NIH Guide to Grants and Contracts NOT-OD-16-094, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html.)

Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, NIH funds may not be used to pay for the cost of the duplicate review.

INFORMATION: As a reminder, it is the responsibility of the grant recipient to ensure that authorization agreements (also called reliance agreements) are in place and copies of authorization agreements and other necessary documentation are maintained by the awardee in order to document compliance with this policy, as needed.

DATA AND SAFETY MONITORING: This grant has been identified as requiring a Data and Safety Monitoring Plan (DSMP) in accordance with the NIAAA Data and Safety Monitoring Guidelines at http://www.niaaa.nih.gov/research/guidelines-and-resources/data-and-safety-monitoring-guidelines. The NIAAA Program Official named below has approved the DSMP as submitted by the grant recipient. Any changes in the DSMP must be reviewed and approved by the NIAAA Program Official.

DISSEMINATION PLAN: The clinical trial(s) supported by this award is subject to the plan submitted to NIH **11/14/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information (see NOT-OD-16-149). The policy states that the clinical trial(s) funded by a NIH award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the AOR (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance

A bi-annual report including the elements listed below should be submitted electronically to the NIAAA Program Official (PO) and the NIAAA Grants Management Specialist listed below every 6 months from the date of grant award. If the reporting due date falls within 60 days of the annual RPPR, please use the RPPR to submit the below reporting elements already included in the RPPR and submit all other elements (*) via email from the Institutional AOR to the NIAAA Grants Management Specialist and Program Officer named below.

The following elements should be included in all annual and interim reports:
• Updated "actual" and "target" inclusion table
• Cumulative listing (no PHI)*

- adverse events
- serious adverse events
- protocol deviations since last reporting period

• DSMB meeting updates/minutes (if applicable)*
• Target milestone updates (if applicable)*
• Issues that could impact the study/completion of the grant*
• Proposed resolution of issues*
• Proposed work during next reporting period

The following target milestones have been established and approved by the PO. Any revisions to approved milestones require PO concurrence and approval. Recruitment is anticipated to begin 01/2025 and complete in nine months..

Enrollment Milestones (n=100):
25% (25) = 03/2025
50% (50) = 05/2025
75% (75) = 07/2025
100% (100) = 10/2025
Data lock: 05/2026

NIAAA DATA ARCHIVE (NIAAADA) DATA SHARING PLAN: This award is subject to the data sharing guidance outlined in NOT-AA-22-011 (https://grants.nih.gov/grants/guide/notice-files/NOT-AA-22-011.html). The Recipient agrees to adhere to the NIAAADA Data Sharing Plan (DSP) as approved by the NIAAA Program Official assigned to this award. Dissemination of study

data will be in accord with the Recipient's approved DSP. Please note that a statement of progress on the DSP must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing" at https://grants.nih.gov/grants/rppr/index.htm.

Failure to adhere to the DSP as mutually agreed upon by the Recipient and the NIAAA may result in Enforcement Actions as described in the NIH Grants Policy Statement at https://grants.nih.gov/policy/nihgps/index.htm.

Complete NIAAADA Data Sharing Terms and Conditions can be found at https://nda.nih.gov/niaaa/data-sharing-expectations.html.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R34AA030662-01A1 REVISED

INSTITUTION: University of Colorado Colorado Springs

Budget	Year 1
Salaries and Wages	$182,211
Fringe Benefits	$61,770
Personnel Costs (Subtotal)	$243,981
Consultant Services	$12,181
Travel	$3,852
Other	$77,005
Subawards/Consortium/Contractual Costs	$149,733
TOTAL FEDERAL DC	$486,752
TOTAL FEDERAL F&A	$166,529
TOTAL COST	$653,281

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	46%
F&A Cost Base 1	$362,019
F&A Costs 1	$166,529

EXHIBIT F

National Institutes of Health
Office of Extramural Research

3/21/2025

Michael Sanderson

University Of Colorado

msander3@uccs.edu

Dear Michael Sanderson:

Effective with the date of this letter, funding for Project Number 1R34AA030662-01A1 is hereby terminated pursuant to the Fiscal Year 2023 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2023 Policy Statement applies to your project because NIH approved your grant on 9/1/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2023 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-

[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.

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

---

[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)

required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

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

Michelle G. Bulls, on behalf of Judy Fox, Chief Grants Management Officer, NIAAA

Director, Office of Policy for Extramural Research Administration

Office of Extramural Research

[12] 12 *Id.* § 50.406(b)

EXHIBIT G

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Notice of Award
FAIN# R34AA030662
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
THE REGENTS OF THE UNIVERSITY OF COLORADO
1420 AUSTIN BLUFFS PKWY
COLORADO SPRINGS, CO 80918

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1846000555E7

4. Employer Identification Number (EIN)
846000555

5. Data Universal Numbering System (DUNS)
186192829

6. Recipient's Unique Entity Identifier
RH87YDXC1AY5

7. Project Director or Principal Investigator
Heather Littleton, PHD (Contact)

hlittlet@uccs.edu
252-916-2976

8. Authorized Official
Michael Sanderson
msander3@uccs.edu
719-255-3034

Federal Agency Information

9. Awarding Agency Contact Information
Donna Stringfield

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
donna.stringfield@nih.gov
(301) 443-3851

10. Program Official Contact Information
Tatiana Nikolayevna Balachova

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
tatiana.balachova@nih.gov
301-443-5726

Federal Award Information

11. Award Number
1R34AA030662-01A1

12. Unique Federal Award Identification Number (FAIN)
R34AA030662

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Online Family-based Program to Prevent Alcohol Use and Dating and Sexual Violence among Sexual and Gender Minority Youth

15. Assistance Listing Number
93.273

16. Assistance Listing Program Title
Alcohol Research Programs

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/01/2023 **– 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	$653,281
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$653,281
26. Project Period Start Date 09/01/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$653,281

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Judy Fox

30. Remarks

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

Notice of Award

CLINICAL TRIAL PLANNING GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

SECTION I – AWARD DATA – 1R34AA030662-01A1 REVISED

Principal Investigator(s):
Katie M Edwards, PHD
Heather Littleton (contact), PHD

Award e-mailed to: osp@uccs.edu

Dear Authorized Official:

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

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Alcohol Abuse And Alcoholism of the National Institutes of Health under Award Number R34AA030662. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

Judy Fox
Grants Management Officer
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Additional information follows

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

Salaries and Wages	$182,211
Fringe Benefits	$61,770
Personnel Costs (Subtotal)	$243,981
Consultant Services	$12,181
Travel	$3,852
Other	$77,005
Subawards/Consortium/Contractual Costs	$149,733
Federal Direct Costs	$486,752
Federal F&A Costs	$166,529
Approved Budget	$653,281
Total Amount of Federal Funds Authorized (Federal Share)	$653,281
TOTAL FEDERAL AWARD AMOUNT	$653,281
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$653,281	$653,281

Fiscal Information:
Payment System Identifier: 1846000555E7
Document Number: RAA030662A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023
AA	8484370	$653,281

NIH Administrative Data:
PCC: AP TD / **OC**: 41021 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:05:56 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R34AA030662-01A1 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R34AA030662-01A1 REVISED

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

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

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

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to

report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) R34AA030662. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at:
http://grants.nih.gov/grants/policy/policy.htm#gps.

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

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

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

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 – AA SPECIFIC AWARD CONDITIONS – 1R34AA030662-01A1 REVISED

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: It is the policy of NIH not to prioritize gender identity. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. Therefore, this project is terminated. The University of Colorado may request funds to support patient safety and orderly closeout of the project. Funds used to

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

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

****

REVISION:

Revised to 1) correct budget and project period end dates to 08/31/2026 and 2) add the following Multi-year funded term:

CHANGE TO A MULTI-YEAR FUNDED AWARD: Although the application upon which this grant is awarded was submitted as a three-year grant request, in order to meet NIAAA program priorities and objectives in Fiscal Year 2023, this grant has been converted to a **multi-year funded award**, with all years of funding provided in the current fiscal year. Special monitoring requirements specific to multi-year funded awards, including the progress report due on or before the anniversary of the budget/project period start date of the award, are detailed in Section III in this Notice of Award.

****

Based on a review of your application and the need to effect NIAAA budgetary and programmatic goals, your requested direct cost funding has been adjusted.

SALARY LIMITATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the applicable salary cap. Therefore, this award and/or future years are adjusted accordingly, if applicable. Current salary cap levels can be found at https://grants.nih.gov/grants/policy/salcap_summary.htm.

PRIOR APPROVALS: In keeping with NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html), as this grant has multiple Principal Investigators (PIs), although the signatures of the PIs are not required on prior approval requests submitted to the agency, the grant recipient institution must secure and retain the signatures of all PIs following their own internal processes.

CONSORTIA: This award includes funds awarded for consortium activity with **University of Nebraska-Lincoln**. Consortia are to be established and administered as described in the NIH Grants Policy Statement (see http://grants.nih.gov/grants/policy/policy.htm#gps).

HUMAN SUBJECTS--VULNERABLE POPULATIONS: The research supported by this award involves a population of human subjects identified as **"vulnerable"**. Investigators who conduct research involving vulnerable populations, including pregnant women, human fetuses and neonates, prisoners, or children must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR Part 46, respectively, which describe the additional protections required for these populations (https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm).

INFORMATION: In accordance with the NIH Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research, it is expected that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a Single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. This grant is expected to develop and participate in a collaborative, central, or shared IRB that will streamline IRB approval while maintaining appropriate human subjects protections. This award reflects the National Institute on Alcohol Abuse and Alcoholism's (NIAAA's) acceptance of the sIRB

plan submitted in the competing application. (See NIH Guide to Grants and Contracts NOT-OD-16-094, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html.)

Participating sites are expected to rely on the sIRB to satisfy the regulatory requirements relevant to the ethical review. Although IRB ethical review at a participating site would be counter to the intent and goal of this policy, the policy does not prohibit any participating site from duplicating the sIRB. However, NIH funds may not be used to pay for the cost of the duplicate review.

INFORMATION: As a reminder, it is the responsibility of the grant recipient to ensure that authorization agreements (also called reliance agreements) are in place and copies of authorization agreements and other necessary documentation are maintained by the awardee in order to document compliance with this policy, as needed.

DATA AND SAFETY MONITORING: This grant has been identified as requiring a Data and Safety Monitoring Plan (DSMP) in accordance with the NIAAA Data and Safety Monitoring Guidelines at http://www.niaaa.nih.gov/research/guidelines-and-resources/data-and-safety-monitoring-guidelines. The NIAAA Program Official named below has approved the DSMP as submitted by the grant recipient. Any changes in the DSMP must be reviewed and approved by the NIAAA Program Official.

DISSEMINATION PLAN: The clinical trial(s) supported by this award is subject to the plan submitted to NIH **11/14/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information (see NOT-OD-16-149). The policy states that the clinical trial(s) funded by a NIH award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the AOR (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance

A bi-annual report including the elements listed below should be submitted electronically to the NIAAA Program Official (PO) and the NIAAA Grants Management Specialist listed below every 6 months from the date of grant award. If the reporting due date falls within 60 days of the annual RPPR, please use the RPPR to submit the below reporting elements already included in the RPPR and submit all other elements (*) via email from the Institutional AOR to the NIAAA Grants Management Specialist and Program Officer named below.

The following elements should be included in all annual and interim reports:
• Updated "actual" and "target" inclusion table
• Cumulative listing (no PHI)*

- adverse events
- serious adverse events
- protocol deviations since last reporting period

• DSMB meeting updates/minutes (if applicable)*
• Target milestone updates (if applicable)*
• Issues that could impact the study/completion of the grant*
• Proposed resolution of issues*
• Proposed work during next reporting period

The following target milestones have been established and approved by the PO. Any revisions to approved milestones require PO concurrence and approval. Recruitment is anticipated to begin 01/2025 and complete in nine months..

Enrollment Milestones (n=100):
25% (25) = 03/2025
50% (50) = 05/2025
75% (75) = 07/2025
100% (100) = 10/2025
Data lock: 05/2026

NIAAA DATA ARCHIVE (NIAAADA) DATA SHARING PLAN: This award is subject to the data sharing guidance outlined in NOT-AA-22-011 (https://grants.nih.gov/grants/guide/notice-files/NOT-AA-22-011.html). The Recipient agrees to adhere to the NIAAADA Data Sharing Plan (DSP) as approved by the NIAAA Program Official assigned to this award. Dissemination of study data will be in accord with the Recipient's approved DSP. Please note that a statement of progress on the DSP must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing" at https://grants.nih.gov/grants/rppr/index.htm.

Failure to adhere to the DSP as mutually agreed upon by the Recipient and the NIAAA may result in Enforcement Actions as described in the NIH Grants Policy Statement at https://grants.nih.gov/policy/nihgps/index.htm.

Complete NIAAADA Data Sharing Terms and Conditions can be found at https://nda.nih.gov/niaaa/data-sharing-expectations.html.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R34AA030662-01A1 REVISED

INSTITUTION: University of Colorado Colorado Springs

Budget	Year 1
Salaries and Wages	$182,211
Fringe Benefits	$61,770
Personnel Costs (Subtotal)	$243,981
Consultant Services	$12,181
Travel	$3,852
Other	$77,005
Subawards/Consortium/Contractual Costs	$149,733
TOTAL FEDERAL DC	$486,752
TOTAL FEDERAL F&A	$166,529
TOTAL COST	$653,281

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	46%
F&A Cost Base 1	$362,019
F&A Costs 1	$166,529