

# EXHIBIT 19

**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 BRITTANY CHARLTON**

I, Brittany Charlton, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. My name is Brittany Charlton. I am an Associate Professor at Harvard Medical School and the Harvard T.H. Chan School of Public Health and Founding Director of the LGBTQ Health Center of Excellence. As an internationally recognized expert in lesbian, gay, bisexual, transgender, and queer (LGBTQ) health, particularly cancer and reproductive health outcomes, I have focused my career on producing data-driven research to inform clinical practice and public policy.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. I was raised in a family of proud union nurses who believed deeply in service, fairness, and standing up for those in need. Therefore, I was called to public health through years of academic work, advocacy, and frontline healthcare within LGBTQ communities. For example, I proudly served a year in AmeriCorps at an LGBTQ-focused community health center, providing HIV counseling and cancer screenings, training physicians in respectful, evidence-based care, and supporting LGBTQ teen moms as a birth doula. I then earned my MSc and ScD in epidemiology from the Harvard T.H. Chan School of Public Health.

4. Before age thirty, Harvard Medical School and the Harvard Chan School of Public Health recruited me to their faculties. I have published over 100 research papers in top medical journals, including *The Journal of the American Medical Association (JAMA)*, *The BMJ*, and the *American*

*Journal of Preventive Medicine*. My work has been cited over 2,600 times. I have mentored over seventy-five faculty, postdoctoral fellows, and trainees, earning international recognition for my commitment to developing the next generation of scientists. A year ago, I launched the LGBTQ Health Center of Excellence—an initiative to advance health equity through an academic center that trains future leaders, drives innovative research, and informs public policy.

5. With a proven ability to win and manage federal grants, I was prepared to secure the funding needed to establish a lasting academic center. Over the past fifteen years, I have received continuous National Institutes of Health (NIH) funding, securing more than fifteen grants. I was awarded a large-scale R01 grant early in my career, an uncommon achievement. NIH grant applications are incredibly demanding. Preparing one can take months or even years and involves entire teams of scientists and staff. Proposals often exceed 200 pages and must make a compelling case that the health issue being studied is urgent and nationally significant. Applicants must prove that their proposed methods are the best possible approach to solve the problem. They must also demonstrate that their team is uniquely qualified. Every application undergoes rigorous peer review by experts, and funding rates are low—especially for R01 grants, where many researchers apply multiple times before ever being funded. Securing a grant is not just about money—it is a hard-won endorsement of a project’s scientific importance, methodological rigor, and real-world potential to improve public health.

6. Since March 2025, NIH has terminated my entire portfolio of grants; I was the sole principal investigator for three of these grants and co-investigator of two others. For each grant, NIH stated in a termination notice that the project “no longer effectuates agency priorities.” The total NIH funding allocated in those five multi-year grants was approximately \$16 million; the early terminations resulted in roughly \$6 million in lost funding as the projects were still underway. To put this loss in perspective, I rank as the fifty-first most highly funded NIH investigator compared to the nearly 500 faculty across Harvard’s thirteen schools (e.g., Harvard College, Harvard Medical School, Harvard Chan School of Public Health). Terminating my entire portfolio has been no minor adjustment, but rather the abrupt defunding of one of the most federally supported research programs in LGBTQ health in the world.

7. One of these terminated grants was an “R61” grant (R61HD117134), aimed at time-sensitive policy questions, to study the impact of discriminatory and supportive legislation on the mental health of LGBTQ young people. NIH reviewers scored the grant application in the top

twelfth percentile, and it was approved for \$4.15 million in costs over five years; it should have received an automatic no-cost extension for a sixth year.

8. A true and correct copy of this R61 grant's Notice of Award (i.e., NOA) is attached as Exhibit A.

9. The overarching goal of the R61 project was to understand how four types of LGBTQ-related policies—religious exemptions, healthcare bans, restrictive curricula, and supportive curricula—impact mental health in late adolescence and early adulthood. The findings would offer timely, evidence-based guidance to help healthcare providers, educators, and policymakers improve mental health for all young people, not just those who are LGBTQ.

10. To complete the project's research aims, our team collected time-sensitive data from the Healthy Minds Study—the largest mental health survey of U.S. college students. We used these data to examine how policies and stigma are linked to mental health, with results disaggregated for LGBTQ and non-LGBTQ students. We then conducted in-depth interviews with individuals directly impacted by these policies. Next, we used nationally representative Behavioral Risk Factor Surveillance System data to estimate the effects of supportive and discriminatory policies among the entire U.S. population. In future years, we were going to apply quasi-experimental methods to quantify the causal impact of such policies on mental health.

11. Over a quarter of U.S. young adults identify as LGBTQ and face disproportionate rates of depression, anxiety, and suicide compared to their peers. The wave of state policies targeting LGBTQ people continues to grow—more than 500 such bills were proposed in state legislatures in 2024 alone. This study was built on my prior research on mental health disparities that arise from such structural stigma and discrimination. We aimed to guide urgently needed interventions that improve mental health and help vulnerable, underserved communities—goals squarely aligned with NIH's stated priorities.

12. Applying for the R61 grant was an intense and compressed process. The funding opportunity, not to mention the research, was time-sensitive. We had only months to write the application to secure five years of funding. The process demanded deep expertise, coordination with collaborators across the U.S., and attention to detail to meet NIH's rigorous standards. I had to set aside personal milestones like family events, celebrations, and other professional obligations to develop a competitive application under significant time pressure. The research topic was meaningful to me and the broader LGBTQ community, of which I am a member; therefore, I felt

the sacrifice was worthwhile at the time. A true and correct copy of a printout of the R61 funding announcement, accessed April 18, 2025, is attached as Exhibit B.

13. The funded project launched on August 26, 2024. Before the termination, I had never received any previous indication that my grant was in jeopardy.

14. The R61 grant supported about a third of my time.

15. Less than eight months into the five-year project, NIH issued a termination notice on March 12, 2025, stating that the award “no longer effectuates agency priorities.” A true and correct copy of the R61 termination notice is attached as Exhibit C.

16. Two days later, on March 14, 2025, I received a revised Notice of Award reflecting the R61 grant’s termination and echoing the termination letter’s language. A true and correct copy of the revised Notice of Award is attached as Exhibit D.

17. Neither the revised Notice of Award nor the termination notice included any individualized explanation for why NIH cancelled the grant, and both failed to discuss the grant application, progress reports, or other related materials (despite the project’s exceptional documented productivity, including advancement ahead of proposed timelines, publication of results, and ongoing dissemination efforts). Instead, the termination notice stated:

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 program. [*sic*]

Ex. C at 1; *see also* Ex. D at 5.

18. I do not understand what the termination notice and revised Notice of Award mean by “gender identity” or “biological realities” concerning my project. When I reached out to my NIH Program Officer—the PhD-level scientific staff member responsible for overseeing and supporting funded research projects—she confirmed that she was not consulted about the termination of my grant. She also stated that she had never witnessed such terminations in her nine years at the agency. She expressed that the process surrounding my grant’s termination was highly unusual. She explained that the National Institute of Child Health and Human Development (“NICHD”) scientific staff typically oversee and manage grants. But, in this case, they were given no information about how awards were selected for termination, what criteria were used, or who made the decisions. She emphasized that program staff like her were not even notified of the termination until the revised Notice of Award was issued following the termination letter, describing this

sequence as far outside the norm. This Program Officer expressed that she did not understand how anonymous decision-makers not familiar with the details of the project had concluded that “no corrective action is possible” or that the project conflicted with agency priorities—particularly as I had responded to a specific Notice of Funding Opportunity that sought out projects addressing this particular topic. She also stated that, if given a chance to appeal, she believed our team could propose feasible modifications, emphasizing that the project was not focused on “gender identity” but rather on the health effects of policies related to sex and gender.

19. As a mid-career researcher familiar with NIH processes and norms, I know that early termination under these circumstances is highly unusual and inconsistent with established precedent. It is extremely rare for a grant to be terminated mid-project, I have only ever seen this happen when an investigator has engaged in misconduct or a research participant (e.g., patient) has been harmed.

20. What is happening now with NIH grant terminations is markedly different: research participants are being put at risk because NIH has abruptly withdrawn support. For example, in the case of a randomized controlled trial, this support is being withdrawn partway through their treatment, allowing for no oversight of the close-out process. It has taken over a month of daily meetings, including with institutional leadership and staff, as we tried to make sense of the termination and to formulate a plan for how to responsibly close out the project while safeguarding the health and well-being of the study participants. Closing out a large study—especially midstream—requires tremendous effort: reviewing protocols, contacting participants, and protecting data integrity. The lack of an orderly process could result in real harm, and my research team is struggling without guidance to safeguard study participants.

21. At the time NIH terminated the R61 grant, my team was actively conducting sensitive, in-depth interviews with young people across the U.S. whose mental health was directly impacted by discriminatory and supportive legislation. Participants were sharing intensely personal stories about the toll of living under policies such as “Don’t Say Gay” laws—stories they may not feel safe disclosing again. We were forced to cancel multiple interviews scheduled for the next day, without explanation. This sudden disruption jeopardized the emotional well-being of already vulnerable young people and raised serious ethical concerns. Such abrupt cancellations risk increasing distress among participants who were already actively struggling with their mental health. The termination shattered a real-time study to document a rapidly evolving public health crisis. As a result, we risk losing valuable firsthand accounts during a pivotal period. The loss

would constitute a blind spot in the scientific record and a missed opportunity to inform urgently needed health and policy interventions.

22. I had also received an R01 grant (R01MD015256) awarded to my institution, titled *Sexual orientation-related disparities in obstetrical and perinatal health*. A true and correct copy of the Notice of Award for this R01 grant is attached as Exhibit E. The project was a “longitudinal study” following a population over time. We designed the study to quantify obstetrical and perinatal health disparities between lesbian/bisexual women and their heterosexual peers (notably, the study did not include transgender participants). Lesbian/bisexual women and their children account for an estimated 800,000 births annually across the country. Prior research found that LGBTQ women have more risk factors (e.g., depression, substance use) for adverse obstetrical and perinatal outcomes compared to heterosexual women. The hypothesis that this study was designed to test was that lesbian and bisexual mothers are subjected to unique forms of stigma, prejudice, and discrimination. Therefore, this research filled a gap in our understanding; little is known about how pregnancy outcomes—not to mention the baby’s health—differ across sexual orientation groups. Studying groups, like lesbian/bisexual women, that experience disproportionately high rates of adverse outcomes allows scientists to identify risk factors. Our preliminary research has revealed that lesbian/bisexual women have higher rates of adverse pregnancy outcomes than their heterosexual peers, making their inclusion essential.

23. In 2020, NIH reviewers scored the grant application in the top seventh percentile, and the project was approved for \$4.42 million in funding over five years; it should have received an automatic no-cost extension for a sixth year.

24. The research took advantage of three unique, ongoing longitudinal, intergenerational cohorts: the Nurses’ Health Study 2, their offspring in the Growing Up Today Study 1 and 2, and a third generation of the Growing Up Today Study participants’ children. Our team analyzed obstetrical and perinatal inequities across sexual orientation subgroups, using advanced study designs that allow for intergenerational comparisons. Finally, drawing on well-established research linking chronic stress from discrimination to health outcomes, we examined factors like depression, substance use, and social support to understand what drives health inequities—and where targeted interventions could make the greatest impact.

25. By generating rigorous evidence about research participants’ health needs—including those of lesbian/bisexual women and their heterosexual peers—the study directly supported NIH’s stated goal of identifying and addressing the needs of at-risk populations. Improving the health of

lesbian/bisexual women and their children addresses other major NIH priority areas, such as understanding the mechanisms of inequities. Most importantly, this study was designed to identify targeted interventions that would improve the health of lesbian/bisexual mothers and their children.

26. Applying for the R01 grant was an extraordinarily time-intensive process. I wrote and revised this grant application multiple times, supported by a team of staff, trainees, and collaborators. I applied twice, subjecting the project to rigorous peer review. Securing an R01 grant is widely recognized as a career-defining achievement in biomedical research, with success rates in the single digits and a typical age of first award in the mid-forties.

27. Receiving my grant at age thirty-five was a tremendous honor and turning point in my career. This grant allowed me to hire and retain staff, as well as support myself and my family.

28. Over 50 of my mentees were involved with this project, including faculty, postdoctoral fellows, doctoral degree students, master's degree students, and staff. In 2024 alone, the team published fifteen peer-reviewed scientific papers on various sexual orientation-related health inequities, and we presented the project's conclusions forty-three other times at scientific meetings.

29. The R01 grant supported almost fifty percent of my time.

30. This study was so successful that NIH continued funding this grant for four years; at no point was there any indication that the grant was in jeopardy.

31. Four years into the five-year grant, on February 18, 2025, my institution received a revised Notice of Award reflecting a no-cost two-month extension of the previous year's award until April 30, 2025. I found this highly unusual as no-cost extensions are almost universally granted after the originally funded period for a research grant concludes (at the end of year 5 for a typical R01) to allow remaining work to be completed, and only at the investigator's request. There was little to no context on this unusually limited extension. While my institution planned to contact our NIH-assigned Grants Management Specialist, I proactively contacted my NIH-assigned Program Officer for context; I received no response. I also contacted the Program Officer's supervisor—a Division Director at the National Institute on Minority Health and Health Disparities ("NIMHD")—and received no response.

32. That revised Notice of Award for this R01 grant was the last communication that I have received regarding this grant; a true and correct copy of this latest R01 Notice of Award in PDF form is attached as Exhibit F.

33. On March 21, 2025, my institution forwarded me a notice from NIH terminating the grant stating that the award “no longer effectuates agency priorities.” A true and correct copy of the termination letter is attached as Exhibit G. I have redacted my personal email address from the attached exhibit solely to protect my personal identifying information.

34. The termination notice does not include any individualized explanation for why the grant was cancelled. It does not identify any places where we failed to meet any objectives or goals, cites no areas of poor-quality work or scientific misconduct, 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 primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion (“DEI”) studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Ex. G at 1.

35. I do not understand what the notice means by the phrase “diversity, equity, and inclusion (‘DEI’) studies,” and I do not know why NIH believes this project is based on “amorphous equity objectives.” While the project did involve lesbian and bisexual participants, the research focused on studying and developing interventions to improve maternal and perinatal health outcomes for all mothers, including heterosexual women. The only imaginable “equity objective” was that we were trying to improve healthcare for a segment of the population that had been largely ignored despite a greater-than-average rate of poor outcomes. Like any NIH-funded project, our application was required to have very clear objectives, based on established scientific literature.

36. I also do not understand why NIH claims this project does not effectuate agency priorities. In October 2016, after a rigorous, evidence-based review process, NIH officially designated LGBTQ populations (i.e., “sexual and gender minorities”) as a health disparity population—a designation reserved for groups facing significant, documented health disparities. This designation made research on LGBTQ health an explicit NIH priority, reinforcing the importance of studies like mine in addressing national public health needs. A true and correct copy of a printout of the NIH webpage detailing this policy, accessed April 18, 2025, is attached as Exhibit H. I developed this project in part because it was directly aligned with NIH’s stated research priorities at the time and responded to explicit calls for work in this area.

37. As outlined above, terminating my R01 grant under these circumstances is a stark departure from established NIH norms and precedent.

38. This project supported an entire research team, many of whom built their careers on the work it enabled. For me, this research represented over two decades of dedication to addressing reproductive health inequities in LGBTQ populations—an area of study that has historically been ignored. The grant allowed dozens of students and trainees to publish papers, gain clinical insight, and pursue careers in medicine and public health.

39. Further benefits from this project are now at risk. Critical findings, such as data showing that lesbians are nearly three times as likely to experience stillbirth as heterosexual women, may never be published—a waste of the taxpayer dollars that funded years of prior research. Without the support from this grant, the trainees leading the study no longer have the salary support or institutional backing to complete data analysis and manuscript preparation. They face serious career setbacks, job insecurity, and financial instability, and they cannot finish their work. They may have no peer-reviewed publications, no tangible outcomes from their pre- and postdoctoral training, and significantly reduced chances of securing future funding or jobs. This means the research will sit unfinished, and its potential to save lives will be lost. This is not just an academic loss—it means more patients will suffer harm, more pregnancies will end in preventable stillbirths, and systemic inequities will remain unaddressed.

40. Tied to my R01 grant was an administrative supplement grant (R01MD015256) of approximately \$100,000, titled *Improving service delivery models of medically assisted reproduction: A patient journey mapping study of sexual minority women couples' experience of medicalized family formation*. This award was to support an advanced postdoctoral fellow on our research team. This grant would have enabled her to have the necessary final year of postdoctoral training before moving into a faculty role, providing a sound footing for her future career. This opportunity is now lost to her. A true and correct copy of the R01 administrative supplement grant's Notice of Award is attached as Exhibit I.

41. The supplemental grant project was designed to study how LGBTQ couples form families. It recognized the specialized fertility services they may require and the negative experiences they may encounter in accessing fertility care. The overall goal was to help other LGBTQ couples seeking to start a family.

42. Our research team conducted semi-structured interviews with LGBTQ couples trying to become pregnant, capturing in-depth qualitative data on their fertility care. These data were paired

with quantitative assessments, such as measures of mental health and healthcare history, for a robust, mixed-methods analysis.

43. To provide an intuitive understanding of LGBTQ patients seeking fertility care, we planned to use a human-centered research method known as journey mapping. It visually charts how an individual interacts with a system—such as reproductive healthcare—to identify key barriers and facilitators in their experience. A central aim of the study was to translate this data into actionable insights for fertility clinics. The project aimed to increase providers’ awareness and empathy of the distinctive burdens faced by women in same-sex couples navigating fertility care, with the goal of improving clinical practices and patient experiences. The study was also designed to develop best practices for inclusive data collection in national cohort studies, laying the groundwork for future large-scale research on preconception and perinatal health inequities.

44. This project directly addressed the core objectives outlined in the NIH Sexual and Gender Minority Research Office’s funding announcement (i.e., Notice of Special Interest), which solicited administrative supplements to expand existing research projects to incorporate LGBTQ populations or LGBTQ-relevant research questions. The funding announcement explicitly prioritized research in high-need areas identified through NIH’s own portfolio analysis. The project’s aims were fully aligned with NIH’s stated scientific and policy goals—namely, to ensure the inclusion of LGBTQ populations in rigorous, data-driven studies. A true and correct copy of a printout of the Notice of Special Interest webpage, accessed April 18, 2025, is attached as Exhibit J.

45. Applying for the R01 administrative supplement was an enormous undertaking, despite the relatively small funding amount. As a mid-career investigator, I typically would not write a grant for \$100,000 due to the high time and resource demands—it requires support from a whole team of staff and scientists. I donated significant staff and personal time to pursue this supplement to support an exceptional trainee with a compelling idea and no other funding source. We collaborated closely on the submission because this award would allow her to extend her postdoctoral training and pursue promising research that could serve as a springboard for her future career.

46. On March 21, 2025, before the project could fully get off the ground, my institution forwarded me a notice from NIH terminating the grant stating that the award “no longer effectuates agency priorities.” A true and correct copy of my termination notice is attached as Exhibit K. I

have redacted my personal email address from the attached exhibit solely to protect my personal identifying information.

47. There was no reference to the scientific merits of the proposal, the project's aims, or any materials submitted in our application. Instead, the termination notice relied solely on generalized language, offering no substantive explanation or evidence-based rationale for the decision. The termination notice stated:

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. K at 1.

48. As above, I was never given any previous indication that this grant was in jeopardy, and termination under these circumstances is highly unusual and inconsistent with NIH precedent.

49. As with the termination notices for the grants described above, I do not understand why NIH believes this project is based on "gender identity." The project's primary focus is on women in same-sex couples trying to become parents. I also do not understand what the notice means by "biological realities." The project was open to any participants who could become pregnant (potentially including transgender participants, though the project did not progress far into the phase of participant recruitment). We focused on how LGBTQ women form families and the ways these women may receive different or substandard obstetrical and gynecological care that could put their health at risk or interfere with their ability to form families. I also do not understand why NIH believes this project does not effectuate agency priorities, as agency guidance indicated that research concerning LGBTQ people was an NIH priority.

Ex. H.

50. This grant's termination has effectively derailed the career trajectory of a talented postdoctoral fellow who is not only a member of the LGBTQ community but also poised to become a future leader in this field. She turned down other career opportunities to commit to this project. The grant's termination abruptly eliminated her salary support and prevented the research from fully launching; at this point, the timeline has passed, and the opportunity is lost. This fellow's success would have advanced research into health disparities and positioned me to mentor another

postdoctoral fellow through a successful faculty transition—mentorship that would have been an additional benefit to me to advance my career from Associate Professor to Professor.

51. Because of the loss of my entire portfolio of grants, I have lost nearly all my salary and the money to pay the wages of about eighteen people in my organization who directly or indirectly support these research studies. I have already had to terminate a senior team member and fear I will have to terminate all remaining team members. Faculty and staff based at our study's subsites (i.e., Boston Children's Hospital, Harvard T.H. Chan School of Public Health, Brigham and Women's Hospital, University of Utah, Boston University) have lost salary support or had their employment terminated.

52. The termination of this research has upended the lives and careers of dozens of my team members—master's students, doctoral students, postdoctoral fellows, faculty, and staff, many of whom relocated or made life-altering commitments to pursue this work. One student has taken medical leave for mental health reasons following our grant terminations and may never return to the field. Another team member—this one more senior in their career—is also on leave, partly due to the stress this upheaval has caused. Some of the brightest scientists in public health and medicine are now being aggressively recruited to academic institutions outside the U.S. Others are leaving academic research and teaching careers entirely. Several have begun rewriting their CVs to downplay their LGBTQ identities or erase the focus of their health equity work, no longer confident that this scholarship is safe or valued. One of our team's senior members confided: "The threats to our work don't just make me fear for my career—they make me fear for my safety. I wonder whether this country still has a place for people like me." These grant terminations are not just the loss of individual careers—it is the quiet dismantling of a generation of future leaders in medicine and public health, and with them, the hope for a more equitable future.

53. Worse still, the breach of trust with our research participants will be exceedingly hard to repair. Many of them entrusted us with highly sensitive information about their lives, and the sudden termination of this grant has made it clear that their contributions were not treated with the seriousness they deserved. Even if funding were restored today, I am not sure these participants would—or should—trust us again.

54. When time-sensitive or long-term studies are cut short, the consequences are lasting. Data becomes unusable, follow-up is lost, and the study's design collapses, undermining current findings and future research. In this case, the termination severed a rare and irreplaceable source of insight into an underserved population. Scientific progress depends on continuity; repairing the

damage once that chain is broken is difficult. As importantly, it is an ethical breach: participants entrusted us with intimate details of their lives, believing their stories would be used for the public good.

55. Scientists who conduct human subjects research are required to complete a course in ethical principles and individual protection. This training is grounded in the Belmont Report, a foundational document that outlines core principles for protecting research subjects: respect for persons, beneficence, and justice. It was developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1978. It serves as the basis for many current research regulations, all of which scientists are mandated to follow. Funding terminations without cause and with no plans or guidance for protecting research subjects have created, at the very least, an ethical breach that cannot be easily repaired.

56. The loss of my entire grant portfolio has crippled the LGBTQ Health Center of Excellence, marking the end of much of Harvard's LGBTQ health research. It is personally and professionally devastating to see the closure of our academic center, which I spent much of my career developing. Worse still, it sends a chilling message to others in the field that research serving marginalized communities is no longer safe or sustainable. This threatens the future of public health and evidence-based medicine. It also puts many individuals at potential risk—including those who are racial/ethnic minorities, low-income, or disabled—without acknowledging their right to health.

57. Following the termination of these grants, the personal toll of standing up for this work has been as devastating—if not more so—as the professional consequences. Since I began speaking out publicly about the importance of safeguarding research into LGBTQ health—before any of my own grants were affected—I have been met with an onslaught of hostility. The harassment has escalated rapidly, invading both my digital life and my private office. I've faced waves of online abuse filled with hate and fear — and disturbingly, threats have arrived at my doorstep, forcing me to tighten home security.

58. These grant terminations have broader implications. When science is silenced by ideology, we all lose. If research on marginalized communities can be erased for political reasons, it sets a dangerous precedent: that some lives are less worthy of understanding, care, or protection. This is not just an attack on the LGBTQ community—it is a blow to the integrity of science and the health of every American.

59. I am actively appealing these terminations, but am at a loss for how to do so. The language used to justify the terminations is vague, making it impossible to understand why this work was

deemed unacceptable or what corrective action one could reasonably take to address any perceived substantive issues. I cannot ethically or responsibly recharacterize my project to meet priorities that have not been clearly defined. I have had to close out work that involves at-risk populations without guidance in an area where the stakes are far too high for guesswork.

60. As I continue to manage closing out these projects, I am aware that success may be impossible: The termination notices assert that the research's premise is fundamentally incompatible with the agency's new priorities, and therefore, truth seems to have become subordinate to ideology—a shift that threatens not just science but the very foundations of democratic inquiry.

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

Executed this 23<sup>rd</sup> day of April, 2025.

  
Brittany Charlton

# EXHIBIT A



## Recipient Information

### 1. Recipient Name

HARVARD PILGRIM HEALTH CARE INC  
1 WELLNESS WAY  
CANTON, MA 02021

### 2. Congressional District of Recipient

08

### 3. Payment System Identifier (ID)

1042452600A1

### 4. Employer Identification Number (EIN)

042452600

### 5. Data Universal Numbering System (DUNS)

071721088

### 6. Recipient's Unique Entity Identifier

NZVVQ8GNVX65

### 7. Project Director or Principal Investigator

Brittany Michelle Charlton, DSC  
Assistant Professor  
bcharlton@mail.harvard.edu  
617-466-9262

### 8. Authorized Official

Cary Williams

## Federal Agency Information

### 9. Awarding Agency Contact Information

Yvonne C. Talley  
Grants Management Official  
EUNICE KENNEDY SHRIVER NATIONAL  
INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT  
talleyy@mail.nih.gov  
301-496-7432

### 10. Program Official Contact Information

Ronna Popkin

EUNICE KENNEDY SHRIVER NATIONAL  
INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT  
ronna.popkin@nih.gov  
301-827-5121

## Federal Award Information

### 11. Award Number

1R61HD117134-01

### 12. Unique Federal Award Identification Number (FAIN)

R61HD117134

### 13. Statutory Authority

42 USC 241 42 CFR PART 52

### 14. Federal Award Project Title

Supportive and restrictive factors and mental health in LGBT adolescent and young  
adult populations

### 15. Assistance Listing Number

93.865

### 16. Assistance Listing Program Title

Child Health and Human Development Extramural Research

### 17. Award Action Type

New Competing

### 18. Is the Award R&D?

Yes

## Summary Federal Award Financial Information

### 19. Budget Period Start Date 08/26/2024 – End Date 07/31/2025

### 20. Total Amount of Federal Funds Obligated by this Action

\$838,837

20 a. Direct Cost Amount

\$694,515

20 b. Indirect Cost Amount

\$144,322

### 21. Authorized Carryover

### 22. Offset

### 23. Total Amount of Federal Funds Obligated this budget period

\$838,837

### 24. Total Approved Cost Sharing or Matching, where applicable

\$0

### 25. Total Federal and Non-Federal Approved this Budget Period

\$838,837

### 26. Project Period Start Date 08/26/2024 – End Date 07/31/2025

### 27. Total Amount of the Federal Award including Approved Cost

\$838,837

Sharing or Matching this Project Period

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Yvonne C. Talley

## 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.



Phase 1 Exploratory/Developmental Grant  
Department of Health and Human Services  
National Institutes of Health

## Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

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### SECTION I – AWARD DATA – 1R61HD117134-01

#### Principal Investigator(s):

Brittany Michelle Charlton, DSC

**Award e-mailed to:** research\_admin@harvardpilgrim.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$838,837 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R61HD117134. 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,

Yvonne C. Talley  
Grants Management Officer  
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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

Salaries and Wages	\$140,347
Fringe Benefits	\$41,823
Personnel Costs (Subtotal)	\$182,170
Consultant Services	\$5,000
Travel	\$6,500
Subawards/Consortium/Contractual Costs	\$500,845
 Federal Direct Costs	 \$694,515
Federal F&A Costs	\$144,322
Approved Budget	\$838,837
Total Amount of Federal Funds Authorized (Federal Share)	\$838,837
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$838,837</b>
 <b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	 <b>\$838,837</b>

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$838,837	\$838,837

**Fiscal Information:**

**Payment System Identifier:** 1042452600A1  
**Document Number:** RHD117134A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2024

IC	CAN	2024
OD	8055729	\$838,837

**NIH Administrative Data:**

**PCC:** PDB -RP / **OC:** 41021 / **Released:** 08/15/2024

**Award Processed:** 08/26/2024 12:12:01 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD117134-01**

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

**SECTION III – STANDARD TERMS AND CONDITIONS – 1R61HD117134-01**

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

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

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

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

research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) R61HD117134. 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](https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf). Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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

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

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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

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

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

#### **Treatment of Program Income:**

Additional Costs

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#### **SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R61HD117134-01**

Clinical Trial Indicator: No

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

#### **TRANSITION PHASE**

In accordance with [PAR-22-233](#), funding for the **R33** phase of this award will be is contingent upon (1) determination that the **R61** goals and milestones were achieved; (2) review and approval of the transition application package; and (3) availability of funds.

The following documentation/information must be provided in the **R33** transition application:

1. Detailed categorical budget and justification for each year of the **R33** phase. Total direct costs cannot exceed the competing application requested amounts or the Integrated Review Group recommended funding levels, if applicable.
2. Milestones section identifying the approved **R61** milestones and the progress towards meeting those milestones.
3. One-page abstract describing the **R3** phase research plan. State if the originally approved aims have been modified or remain the same. If modified, provide a justification for the modifications.

These components are required two months prior to the anticipated start of the **R33** phase. The report should be sent as a single pdf attachment to the Grants Management Specialist and Program Official indicated on this Notice of Award using the [PHS 2590](#) format. The report must be approved by the institutional Signing Official.

The appropriate NICHD Grants Management and Program staff will review the **R33** transition application. If the transition request is not approved, written notification will be sent to the applicant.

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#### Co-fund

This award provides co-funding support in the amount of \$838,837 (\$694,515 direct costs + \$144,322 facilities and administrative costs) from Office of Behavioral and Social Sciences Research (OBSSR).

#### Start Date

This award includes funds for twelve months of support but is awarded for less than twelve months.

#### Human Subjects

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

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

#### Data Management Sharing Plan

Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the **application** dated **02/14/2024**.

#### Graduate Student

The maximum amount that NIH will provide to support the compensation package (salary, fringe benefits and tuition remission) for a graduate student is equal to the zero

level postdoctoral stipend in effect at the time of the completing award, as described in [NOT-OD-02-017](#). This award has been adjusted accordingly.

#### Consortium

This award includes funds awarded for consortium activity with Boston University.

Data Management and Sharing Policy: Applicable

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

#### **SPREADSHEET SUMMARY**

**AWARD NUMBER:** 1R61HD117134-01

**INSTITUTION:** HARVARD PILGRIM HEALTH CARE

Budget	Year 1
Salaries and Wages	\$140,347
Fringe Benefits	\$41,823
Personnel Costs (Subtotal)	\$182,170
Consultant Services	\$5,000
Travel	\$6,500
Subawards/Consortium/Contractual Costs	\$500,845
TOTAL FEDERAL DC	\$694,515
TOTAL FEDERAL F&A	\$144,322
TOTAL COST	\$838,837

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	66%
F&A Cost Base 1	\$218,670
F&A Costs 1	\$144,322

# EXHIBIT B

This notice has expired. For NIH, in limited situations, applications may be accepted on a case-by-case basis for a short period after expiration to accommodate NIH late or continuous submission policies (<https://grants.nih.gov/grants-process/submit/submission-policies>). Contact the eRA Service Desk (<https://www.era.nih.gov/need-help>) for any submission issues. Check the NIH Guide (<https://grants.nih.gov/funding/searchguide/>) for active opportunities and notices.

## Department of Health and Human Services

### Part 1. Overview Information

#### Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

#### Components of Participating Organizations

Office of Behavioral and Social Sciences Research ([OBSSR \(https://obssr.od.nih.gov/\)](https://obssr.od.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA \(https://www.niaaa.nih.gov/\)](https://www.niaaa.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS \(https://www.niams.nih.gov/\)](https://www.niams.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD \(https://www.nichd.nih.gov/\)](https://www.nichd.nih.gov/))

National Institute on Drug Abuse ([NIDA \(https://www.drugabuse.gov/\)](https://www.drugabuse.gov/))

National Institute of Nursing Research ([NINR \(https://www.ninr.nih.gov/\)](https://www.ninr.nih.gov/))

National Institute on Minority Health and Health Disparities ([NIMHD \(https://www.nimhd.nih.gov/\)](https://www.nimhd.nih.gov/))

National Cancer Institute ([NCI \(https://www.cancer.gov/\)](https://www.cancer.gov/))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. OBSSR and the following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention ([ODP \(https://prevention.nih.gov/\)](https://prevention.nih.gov/))

Office of Research on Women's Health ([ORWH \(https://orwh.od.nih.gov/\)](https://orwh.od.nih.gov/))

#### Funding Opportunity Title

**Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed)**

#### Activity Code

[R61 \(//grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r61&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r61&Search.x=0&Search.y=0&Search_Type=Activity)/R33

[\(/grants.nih.gov/grants/funding/ac\\_search\\_results.htm?text\\_curr=r33&Search.x=0&Search.y=0&Search\\_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r33&Search.x=0&Search.y=0&Search_Type=Activity).

Exploratory/Developmental Phased Award

#### Announcement Type

New

#### Related Notices

See [Notices of Special Interest \(https://grants.nih.gov/grants/guide/NOSIs\\_targetingList.cfm?GuideDocID=37757\)](https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=37757) associated with this funding opportunity

**April 04, 2024** - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice [NOT-OD-24-084 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html)

**February 29, 2024** - Notice of Change to Expiration Date for PAR-22-233 Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed). See Notice [NOT-OD-24-065 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html)

**December 01, 2023** - Notice of Change to Expiration Date for PAR-22-233. See Notice [NOT-OD-24-016 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html)

**October 25, 2023** - Notice of Change to Expiration Date for PAR-22-233 Time-Sensitive Opportunities for Health Research (R61/R33 Clinical Trial Not Allowed) . See Notice [NOT-OD-24-016 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-016.html)

[NOT-OD-23-012 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available

[NOT-OD-22-190 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-190.html) - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022

**September 28, 2022** - Notice of Information for Pre-Application Webinar for PAR-22-233. See Notice [NOT-OD-22-222 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-222.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-222.html).

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#### Funding Opportunity Announcement (FOA) Number

PAR-22-233

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#### Companion Funding Opportunity

None

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#### Number of Applications

See [Section III. 3. Additional Information on Eligibility](#).

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#### Assistance Listing Number(s)

93.307, 93.279, 93.399, 93.313, 93.361, 93.273, 93.846, 93.865

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#### Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) establishes an accelerated review/award process to support research to understand health outcomes related to an unexpected and/or time-sensitive event (e.g., emergent environmental threat; pandemic; change in local, state, or national policy; natural disaster). Applications in response to this FOA must demonstrate that the research proposed is time-sensitive and must be initiated with minimum delay due to a limited window of opportunity to collect baseline data, answer key research questions, and/or prospectively evaluate a new policy or program. This FOA is intended to support opportunities in which empirical study could only be available through expedited review and funding, necessitating a substantially shorter process than the typical NIH grant review/award cycle. The time from submission to award is expected to occur within 4-5 months. However, administrative requirements and other unforeseen circumstances may delay issuance dates beyond that timeline.

## Key Dates

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#### Posted Date

September 01, 2022

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#### Open Date (Earliest Submission Date)

November 01, 2022

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#### Letter of Intent Due Date(s)

4 weeks prior to application due date

### Application Due Date(s)

Applications will be accepted on a rolling basis, beginning November 1, 2022. Applications will be accepted through March 1, 2025.

All applications are due by 5:00 PM local time of applicant organization.

### AIDS Application Due Date(s)

Not Applicable

### Scientific Merit Review

Applications will be reviewed within 8 weeks.

### Advisory Council Review

Applications will be reviewed on an expedited basis

### Earliest Start Date

Within 4-6 months of application

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### Expiration Date

**New Date** March 2, 2025 (Original Date: November 02, 2023) per issuance of [NOT-OD-24-065 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-065.html)

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### Due Dates for E.O. 12372

Not Applicable

### Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/uri\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82400), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts \(//grants.nih.gov/grants/guide/uri\\_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=11164)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

**Applications that do not comply with these instructions may be delayed or not accepted for review.**

## Table of Contents

### [Part 1. Overview Information](#)

#### [Key Dates](#)

### [Part 2. Full Text of Announcement](#)

#### [Section I. Funding Opportunity Description](#)

#### [Section II. Award Information](#)

#### [Section III. Eligibility Information](#)

#### [Section IV. Application and Submission Information](#)

#### [Section V. Application Review Information](#)

#### [Section VI. Award Administration Information](#)

#### [Section VII. Agency Contacts](#)

#### [Section VIII. Other Information](#)

## Part 2. Full Text of Announcement

### Section I. Funding Opportunity Description

#### BACKGROUND

This Funding Opportunity Announcement (FOA) establishes an accelerated review/award process to support novel behavioral and social science research (BSSR) to understand health outcomes related to an unexpected and/or time-sensitive event. **Applications in response to this FOA must demonstrate that the research proposed is time-sensitive and must be initiated with minimum delay due to a limited window of opportunity to collect baseline data, answer key research questions, and/or prospectively evaluate a new policy or program that will likely impact health-related behavior or health outcomes in a given population.** In other words, the urgency of the public health problem being studied will not, on its own, be sufficient justification for time sensitivity.

## RESEARCH SCOPE

This FOA is intended to support research and data collection for unanticipated real-world events (i.e., those that occur outside of a laboratory or other controlled setting for research purposes). These events inherently have limited windows of opportunity for planning and conducting rigorous research and data collection. It is critical that researchers maximize these learning opportunities to better inform health care and public health efforts, as well as policymakers.

Key Definitions for this FOA:

- An **event** is a unique and often unanticipated issue that arises in a particular community/population, due to emerging environmental threats, other public health threats, disaster events, or policy changes.
- **Policy** is broadly defined to include both formal public policies at local, state, and federal levels of government, and organizational level policies, such as those implemented by large organizations, worksites, or school districts.
- **Program** is defined as a set of activities such as implementation of system-level interventions, tools, or guidelines initiated by governmental or other organizational bodies, within public or private entities in local, state, or federal jurisdictions.
- **Infrastructure changes** are alterations to the built environment such as housing, roads and other aspects of transportation systems, retail environments, and building of parks or green spaces.

This FOA encourages partnerships and collaboration between researchers and the impacted community, which may include the following types of entities (as appropriate): community-based organizations, local and state governments, private or non-profit organizations, behavioral health or health care systems, individual health care providers, departments of health, community health clinics, juvenile or criminal justice settings, schools, child welfare systems, etc.

The distinguishing features of a responsive study are:

- (1) The unpredictable and unanticipated nature of the research opportunity.
- (2) The clear scientific value and feasibility of the study.
- (3) A feasible plan for collection of baseline data and primary data collection (although use of existing data is allowed, a plan for collecting important and new data rapidly should be provided).
- (4) A justification for why an expedited review and funding (substantially shorter than the typical NIH grant review/award cycle) are required in order for the scientific question(s) to be addressed and the research design to be implemented. Expected study methodologies may include, but are not limited to, interrupted time-series, difference-in-difference designs, regression discontinuity, or propensity scoring.

In situations where applications under this FOA focus on a particular locality (region, community, or other defined geographic area), note that findings should have the potential to be generalizable beyond the particular locality or population. Proposed studies should demonstrate the ability to inform the understanding of the impact of the event, policy, program or infrastructure change in the near-term. Applicants are encouraged to include secondary implementation related outcomes that could inform interpretation of outcomes for future researchers and decision-makers, such as unintended consequences or barriers and facilitators associated with implementation.

Applicants are also encouraged to review the NIH-led efforts that recommend research strategies for ensuring study rigor and reducing bias, such as including an appropriate comparison group where possible: [NIH Pathways to Prevention \(P2P\) Workshop: Method for Evaluating Natural Experiments in Obesity \(https://prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention/methods-evaluating-natural-experiments-obesity\)](https://prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention/methods-evaluating-natural-experiments-obesity). Furthermore, attention should be paid to ongoing developments in strengthening causal inference from evaluation of these natural experiments or observational study designs. Considerable progress has been made on this topic in public health, econometrics, and diverse aspects of policy research.

## STRUCTURE

This FOA will utilize a bi-phasic, milestone-driven R61/R33 mechanism, consisting of a R61 phase with developmental activities and a R33 phase with expanded activities designed to achieve the full research aims. The R61 phase will be up to one year, and will support developmental, exploratory research, Institutional Review Board approval for human subjects protection, further development of study partnerships, and the collection of baseline data. The R33 phase will build on this initial work for up to four years to include further development, application, follow-up data collection, or implementation as appropriate and relevant to the proposed research questions.

The application should articulate clear aims and objectives for each phase of the proposed research, with specific discussion of how results from the R61 phase will inform the R33 phase. In addition, applications must delineate explicit milestones for the R61 and R33 phases. A milestone is defined as a scheduled event in the project timeline that indicates completion of a project stage or activity. **It is expected that**

**baseline data collection will be conducted within six months of award, which should be included in the applicant's submission of a project timeline and milestones.** At the completion of the R61 phase, the Program Director (PD)/Principal Investigator (PI) will submit a report that includes the progress on each of the milestones and a clear description of how research during the R33 phase will be impacted by attainment of the R61 milestones. The IC program and other relevant staff will review the report and make recommendations on funding of the R33 grant based on two independent factors: 1) the preliminary research results and achievement of the milestones and 2) availability of funds and program priorities, irrespective of milestone achievements. Transition to the R33 phase is neither automatic nor guaranteed. Funding for the R33 phase is subject to availability of funds and program priorities, independent of milestone achievement. In addition, given the possibility for changes in policy or program implementation that are beyond the control of the grantee, grant awards may be terminated early if these changes limit the possibility to collect meaningful outcome data.

#### **ADDITIONAL GUIDANCE**

While applicants may propose to investigate time-sensitive opportunities outside the U.S., they must demonstrate within the application that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement. In addition, the applicant must demonstrate how information obtained from this study will have direct implications for US practice or policy.

**Applicants are strongly encouraged to contact the relevant scientific contact(s) listed below to discuss whether their application would likely be responsive based on time-sensitivity four (4) weeks in advance of planned application.**

#### **Applications Not Responsive to this FOA**

**The following types of applications are not responsive to this FOA. Applications not responsive to this FOA will not be reviewed.**

- Applications that do not explicitly justify the time sensitivity of the proposed work, the urgent need for data collection, and the need for an expedited review timeline. Include this explanation in the Significance section of the application.
- Applications that propose to use qualitative data exclusively (though mixed method approaches are encouraged).
- Applications that propose to conduct analyses of existing data exclusively (unless allowed in IC-specific interests).
- Applications aimed at addressing unanticipated needs or additional aims for an existing study (i.e., expansion of an existing study).
- Applications proposing to use animals (e.g., pets, laboratory animals, or wildlife) as surrogates for human health or exposure.
- Applications where the PD/PI of the evaluation study application is the Director and/or initiator of the policy, program, or infrastructure change that will be evaluated.
- Applications that independently propose initiation and/or delivery of new policies or programs.

All responsive applications to this FOA will be subject to an accelerated review and award process. It is intended that eligible applications selected for funding will be awarded within 4-5 months of the application due date. However, administrative requirements and other unforeseen circumstances may delay issuance dates beyond that timeline.

#### **SPECIFIC AREAS OF RESEARCH INTEREST**

##### **National Cancer Institute (NCI)**

NCI supports time-sensitive evaluation of programs, policies, and major events that concern aspects of cancer prevention and control including, but not limited to:

Evaluation of the effects of:

- Laws, regulations, or policies that may influence cancer risk factors including use of tobacco, alcohol, and other substances, sun safety and indoor tanning, diet, physical activity, and sleep.
- Changes to the built and natural environment involving factors such as housing, transportation infrastructure, food environment, parks and other green and blue spaces and the potential effect on cancer risk factors, exposure to environmental carcinogens, access to care, or other cancer-related health outcomes.
- Emerging programs and policies related to cancer screening, diagnosis, vaccination (e.g., HPV), treatment, and survivorship.
- New policies, programs, and practices in cancer care delivery related to standards of care, health insurance coverage, access to services, reimbursement, and other factors that influence delivery of cancer care services and its outcomes
- The impact and response to public health emergencies or disasters (natural or man-made) on acute stress, allostatic load or other aspects of accumulated stress, or cancer-related care, including preventative, diagnostic, treatment, and survivorship care.
- Natural and man-made disasters (e.g., chemical spills, fumes, weather events, and fires), and resulting environmental exposures on biomarkers, etiology, and healthcare delivery across the cancer control continuum.
- Natural and man-made disasters (e.g., chemical spills, fumes, weather events, and fires), and resulting environmental exposures on biomarkers, etiology, and healthcare delivery across the cancer control continuum.

Proposals evaluating policy and program efforts and responses to major events from diverse sectors, including government, educational, non-profit, and commercial sectors are of interest.

##### **Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)**

NICHD has particular interest in research on time-sensitive events, policies, programs, or infrastructure changes on vulnerable populations falling within the NICHD scientific mission area, including infants, children, and adolescents and pregnant and post-partum people; individuals with physical and/or intellectual disabilities; and children who are unhoused or in foster care. The [NICHD Strategic Plan](https://www.nichd.nih.gov/about/org/strategicplan) (<https://www.nichd.nih.gov/about/org/strategicplan>) outlines high priority areas for the Institute.

Examples of research questions include but are not limited to the following:

- Understanding the short- and long-term impact of the time-sensitive event on child development outcomes, as well as family functioning.
- The impact of climate/environmental changes on dietary patterns, food choices, and eating behaviors.
- How changes in access to school lunch programs affect dietary patterns, food choices, and eating behaviors in children and their families.
- The impact of the event and the concomitant public health response on the management of complex medical conditions, critical illness, and severe, life-threatening injuries in children.
- The impact of the event on emergency medical services to children (EMSC) and the availability of these services during and after the event to affected children in low- to moderate- resourced communities.
- Studies identifying and developing data sources, tools and resources needed to strengthen tracking, reporting and communication among systems of care for traumatized, injured and affected children during and after the unexpected event.
- The impact of the event and the concomitant public health response on children and adults with physical and/or intellectual disabilities, and disparities in outcomes experienced by persons with disabilities compared to persons without disabilities.
- Studies that examine how unexpected disruptions in access to therapies and special education services affect developmental, behavioral and functional outcomes in children and adults with disabilities.

#### **National Institute on Drug Abuse (NIDA)**

This notice of funding opportunity (NOFO) will support pilot, feasibility or exploratory research in priority areas in substance use epidemiology, prevention, and health services, including: 1) responses to sudden and severe emerging drug issues (e.g. the ability to look into a large and sudden spike in opioid or synthetic cannabinoid use/overdoses in a particular community); 2) responses to emerging marijuana trends and topics related to the shifting policy landscape, related to imminent policy change; 3) responses to unexpected and time-sensitive prescription drug abuse research opportunities (e.g., new state or local efforts); 4) responses to unexpected and time-sensitive medical system issues (e.g. opportunities to understand addiction services in the evolving health care system); 5) responses to unexpected and time-sensitive criminal or juvenile justice opportunities (e.g. new system and/or structural level changes) that relate to drug abuse and access and provision of health care service; 6) partnerships between researchers and state or local organizations to support the evaluation of new local policies, programs, or practices in response to public health emergencies (e.g., the opioid crisis); 7) research examining how the COVID-19 pandemic has impacted drug markets and overdose risk; 8) research examining health outcomes associated with telehealth compared to in-person psychiatric care (e.g. risk of diversion/misuse, reduced treatment gap); 9) research examining the impact of the discontinuation of the Medicaid continuous enrollment provision that was enacted during the COVID-19 pandemic on populations with substance use disorders, and 10) research to understand outcomes related to states receiving and implementing Centers for Medicare and Medicaid Services (CMS) 1115 waivers that allow Medicaid to pay for health care services in carceral settings.

#### **National Institute on Minority Health and Health Disparities (NIMHD)**

The mission of NIMHD is to lead scientific research to improve minority health and reduce health disparities. NIMHD focuses on all aspects of health and health care for racial and ethnic minority populations in the U.S. and the full continuum of health disparity causes as well as the interrelation of these causes. NIMHD projects should include a focus on racial and ethnic minority populations (African Americans/Blacks, Latinos/Hispanics, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and Pacific Islanders) and or less privileged socioeconomic groups. Projects may also examine intersectionality of race or ethnic minority identity and/or low socioeconomic status with rurality and/or sexual and gender minority identity and/or disability condition. Comparison groups/populations may also be included as appropriate for the research questions posed. NIMHD encourages research projects that use approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities (see the NIMHD Research Framework, <https://www.nimhd.nih.gov/about/overview/research-framework.html>, for more information). Studies based outside the U.S. or its territories will not be supported by NIMHD under this FOA. Time-sensitive research that NIMHD is interested in supporting includes:

- The effects of policy changes on health outcomes, and mechanisms of those health outcomes, in populations that experience health disparities, including: immigration policy, health care coverage, gun policy, police use-of-force policy, environmental regulations, prescribing practices, and vaccination requirements
- The immediate and longer-term impact of natural disasters on the health of populations that experience health disparities (particularly through the lens of understanding how climate change is impacting health disparities)
- Effects of changes to the built environment (e.g., greenspace, pedestrian walkways, bike paths) on health and health behaviors for populations that experience health disparities

#### **National Institute of Nursing Research (NINR)**

NINR supports research to solve pressing health challenges and inform practice and policy - optimizing health and advancing health equity into the future. NINR discovers solutions to health challenges through the lenses of health equity, social determinants of health, population and community health, prevention and health promotion, and systems and models of care. Drawing on the strengths of nursing's holistic, contextualized perspective, core values, and broad reach, NINR funds multilevel and cross-sectoral research that examines the factors that impact health across the many settings in which nurses work, including homes, schools, workplaces, clinics, justice settings, and the community. Observational, intervention, and implementation research are of interest to NINR.

Research is encouraged in the following areas:

- Factors involved in a response to a time-sensitive event that affect health equity, including mechanisms involved.
- Effects of social determinants of health on the response to and health effects resulting from a time-sensitive event.
- Prevention and early detection of health effects of a time-sensitive event, including plans for health promotion during and following the event.
- Examining clinical, organizational and/or policy changes to address health related needs during and following a time-sensitive event.

#### **National Institute on Alcohol Abuse and Alcoholism (NIAAA)**

NIAAA will support time-sensitive research in public health priority areas in alcohol and related substance use epidemiology, prevention, and health services, including but not necessarily limited to:

- time-sensitive research opportunities to study the effects of changes in alcohol-related policies, including effects on combined use of alcohol and other substances and evaluation of the implementation or effectiveness of policies, programs, or practices affecting alcohol-related behaviors and outcomes;
- time-sensitive research opportunities to study changes in factors affecting access, delivery, or financing of health care services for alcohol use disorder and alcohol-related conditions;
- time-sensitive research opportunities to study alcohol-related effects associated with sudden and severe events, such as natural disasters, acts of war, or epidemics;
- time-sensitive research opportunities to study the effects on diversity, health equity, inclusion, or access of unanticipated events affecting alcohol-related behaviors and outcomes; and
- time-sensitive research opportunities to inform state or local organizations of the alcohol-related consequences of new or changing policies, programs, or practices.

#### **National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)**

NIAMS is interested in applications focused on evaluating time-sensitive natural experiments that concern populations with or at risk for development of NIAMS core-mission diseases (arthritis and other rheumatic, musculoskeletal, and skin disorders. Examples include, but are not limited to, time-sensitive natural experiments of changes to the neighborhood food and physical activity environments on the health of populations experiencing or at risk for NIAMS core-mission diseases. Studies among underserved, vulnerable, diverse and health disparities populations are encouraged.

#### **Office of Disease Prevention (ODP)**

The ODP is the lead office at the NIH responsible for assessing, facilitating, and stimulating research in disease prevention. In partnership with the 27 NIH Institutes and Centers, the ODP strives to increase the scope, quality, dissemination, and impact of NIH-supported prevention research. The ODP co-funds research that has strong implications for disease and injury prevention and health equity and that includes innovative and appropriate research design, measurement, and analysis methods. The ODP has a specific interest in projects that develop and/or test preventive interventions. Of particular interest is prevention research addressing leading causes and risk factors for premature morbidity and mortality, dissemination and implementation, and health disparities. The ODP does not award grants; therefore, applications must be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed in this announcement. Please contact the relevant IC Scientific/Research Contact(s) listed for questions regarding IC research priorities and funding. ODP only accepts co-funding requests from NIH Institutes and Centers (ICs). For additional information about ODP, please refer to the [ODP Strategic Plan for Fiscal Years 2019-2023](https://prevention.nih.gov/about-odp/strategic-plan-2019-2023) (<https://prevention.nih.gov/about-odp/strategic-plan-2019-2023>).

#### **Office of Research on Women's Health (ORWH)**

ORWH works with the 27 NIH Institutes and Centers to advance rigorous research of relevance to women and individuals assigned female at birth. For this funding opportunity, ORWH is particularly interested in intersectional research into the health impacts of time-sensitive events, policies, programs, or infrastructure changes on women, including:

- Impacts of policy changes on the health of women and people who can become pregnant (e.g., state abortion regulations, extensions to postpartum insurance coverage)
- Impacts of policy changes that influence access to women's preventative health services (e.g., contraception, HPV vaccination, pre-exposure prophylaxis (PrEP))
- Gender-based violence following time-sensitive events (e.g., natural disasters; pandemics)

See [Section VIII. Other Information](#) for award authorities and regulations.

## Section II. Award Information

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### Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

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### Application Types Allowed

New

The [OER Glossary \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

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### Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)

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### Funds Available and Anticipated Number of Awards

PA/PAR:

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

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### Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

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### Award Project Period

The scope of the proposed project should determine the requested project award period.

The maximum period of the combined R61 and R33 phases is 5 years, with up to 1 year for the R61 phase and up to 4 years for the R33 phase.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) will apply to the applications submitted and awards made from this FOA.

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

#### For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

#### Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

#### Federal Government

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

#### Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

#### Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

### Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11118](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118)), **are** allowed.

### Required Registrations

#### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)), states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [System for Award Management \(SAM\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82390](https://grants.nih.gov/grants/guide/url_redirect.php?id=82390)) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - [NATO Commercial and Government Entity \(NCAGE\) Code](https://grants.nih.gov/grants/guide/url_redirect.php?id=11176) ([//grants.nih.gov/grants/guide/url\\_redirect.php?id=11176](https://grants.nih.gov/grants/guide/url_redirect.php?id=11176)) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11123](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- [Grants.gov \(/grants.nih.gov/grants/guide/url\\_redirect.php?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82300), Applicants must have an active SAM registration in order to complete the Grants.gov registration.

### Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

### Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement \(/grants.nih.gov/grants/guide/url\\_redirect.php?id=11126\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11126).

## 3. Additional Information on Eligibility

### Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [2.3.7.4 Submission of Resubmission Application \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_2/2.3.7\\_policies\\_affecting\\_applications.htm#Submissi\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.7_policies_affecting_applications.htm#Submissi). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [2.3.9.4 Similar, Essentially Identical, or Identical Applications \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_2/2.3.9\\_application\\_receipt\\_information\\_and\\_deadlines.htm#Similar\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3.9_application_receipt_information_and_deadlines.htm#Similar)).

## Section IV. Application and Submission Information

### 1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in [Part 1. Overview Information](#), prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Rosalind King, PhD  
Office of Behavioral and Social Sciences Research (OBSSR)  
Phone: 301-451-3832  
Email: [kingros@nih.gov](mailto:kingros@nih.gov) (<mailto:kingros@nih.gov>)

## Page Limitations

All page limitations described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url\\_redirect.php?id=11133\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11133) must be followed.

## Instructions for Application Submission

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing (DMS) Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

## SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

## SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

## SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

## SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

## R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

## R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

## PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

## PHS 398 Research Plan

### Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H and subsequent application forms packages. For due dates on or before January 24, 2023, the Data Sharing Plan and Genomic Data Sharing Plan GDS) will continue to be attached in the Resource Sharing Plan attachment in FORMS-G application forms packages.

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

**Research Strategy:** Applications should justify the time sensitivity of the proposed work, the urgent need for data collection, and the need for an expedited review timeline in the Significance section of the application.

The Research Strategy should include a description of both the R61 and R33 phases, each with clear aims and objectives. Include a specific section labeled "Milestones". Milestones should be clearly described, feasible, well developed, quantifiable, and scientifically justified to transition to the R33 phase. A discussion of the milestones relative to the progress of the R61 phase and the implications of successful completion of the milestones for the R33 phase should be included. **It is expected that baseline data collection will be conducted within six months of award, which should be included in the applicant's submission of a project timeline and milestones.**

If applicable and proposing to investigate time-sensitive opportunities outside the U.S., the application must include information demonstrating that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed

within the limited time frame outlined in this announcement. In addition, the applicant must demonstrate how information obtained from this study will have direct implications for US practice or policy.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

## Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

### PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

#### Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

#### Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

### PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

## 3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

## 4. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission. This FOA accepts applications on a rolling basis. Applications are reviewed on an expedited schedule and assigned to an Advisory Council round based on their actual submission date. Because the Scientific Merit Review assignment deadline listed in Part 1. Key Dates is not an application due date, the NIH Policy on Late Application Submission does not apply to the Scientific Merit Review or Advisory Council round assigned.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

## 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review \(https://grants.nih.gov/grants/policy/nihgps/html5/section\\_10/10.10.1\\_executive\\_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm).

## 6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/redirect.php?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.php?id=11143\)](https://grants.nih.gov/grants/guide/redirect.php?id=11143).

## 7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. [Section III. Eligibility Information](#) contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See [more tips \(//grants.nih.gov/grants/guide/redirect.php?id=11146\)](https://grants.nih.gov/grants/guide/redirect.php?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review, NIH. Applications that are incomplete, non-compliant or non-responsive will not be reviewed.

## Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/redirect.php?id=82299\)](https://grants.nih.gov/grants/guide/redirect.php?id=82299). Any instructions provided here are in addition to the instructions in the policy.

# Section V. Application Review Information

## 1. Criteria

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission \(//grants.nih.gov/grants/guide/redirect.php?id=11149\)](https://grants.nih.gov/grants/guide/redirect.php?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

## Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

## Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

## Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

## Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

## Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

## Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

**Milestones and timeline:** Is there a unifying research question that transcends both R61 and R33 phases? Does the application provide well described, feasible and quantifiable milestones for the R61 phase and related scientific goals and objectives for the R33 phase? Are those milestones conducive to accomplishing the study aims? Are the goals of the R33 phase based, in part, on findings collected during the R61 phase? Does the timeline demonstrate baseline data collection within six months of award?

## Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

If applicable and proposing to investigate time-sensitive opportunities outside the U.S., is there appropriate justification of how the information obtained from the study will have direct implications for US practice and/or policy? Is there adequate information provided demonstrating that all the proper logistics, human subjects concerns, and approvals, both domestic and international, can be addressed within the limited time frame outlined in this announcement.

## Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

## Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and

3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](https://grants.nih.gov/grants/guide/redirect.php?id=11175) ([//grants.nih.gov/grants/guide/redirect.php?id=11175](https://grants.nih.gov/grants/guide/redirect.php?id=11175)).

## **Inclusion of Women, Minorities, and Individuals Across the Lifespan**

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](https://grants.nih.gov/grants/guide/redirect.php?id=11174) ([//grants.nih.gov/grants/guide/redirect.php?id=11174](https://grants.nih.gov/grants/guide/redirect.php?id=11174)).

## **Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](https://grants.nih.gov/grants/guide/redirect.php?id=11150) ([//grants.nih.gov/grants/guide/redirect.php?id=11150](https://grants.nih.gov/grants/guide/redirect.php?id=11150)).

## **Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

## **Resubmissions**

Not Applicable

## **Renewals**

Not Applicable

## **Revisions**

Not Applicable

## **Additional Review Considerations**

Note: Effective for due dates on or after January 25, 2023, the Data Sharing Plan and Genomic Data Sharing Plan (GDS) as part of the Resource Sharing Plan will not be evaluated at time of review.

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

## **Time Sensitivity**

Reviewers will assess whether or not (i.e., yes/no) applications demonstrate the time sensitivity of the research opportunity; in other words, will an important opportunity for scientific inquiry and data collection be lost if the work is not initiated in an expedited way (i.e., with minimum delay). It should be clear that the knowledge gained from the proposed study is time-sensitive such that an expedited review and funding are required in order for the scientific question(s) to be answered. Reviewers are also asked to determine whether or not the event described in the application offers an uncommon and scientifically compelling opportunity that might only be available through this mechanism. Of particular relevance is that an expedited award would facilitate baseline data collection at a critical point in the timeline of the event in question.

## **Applications from Foreign Organizations**

Not Applicable.

## **Select Agent Research**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

## **Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) [Data Sharing Plan](https://grants.nih.gov/grants/guide/url_redirect.php?id=11151) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11151](https://grants.nih.gov/grants/guide/url_redirect.php?id=11151)); (2) [Sharing Model Organisms](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview) (<https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview>); and (3) [Genomic Data Sharing Plan \(GDS\)](https://sharing.nih.gov/genomic-data-sharing-policy) (<https://sharing.nih.gov/genomic-data-sharing-policy>).

### **Authentication of Key Biological and/or Chemical Resources:**

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

## **2. Review and Selection Process**

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by Center for Scientific Review (CSR) in accordance with [NIH peer review policy and procedures](https://grants.nih.gov/grants/guide/url_redirect.php?id=11154) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11154](https://grants.nih.gov/grants/guide/url_redirect.php?id=11154)), using the stated [review criteria](https://grants.nih.gov/grants/guide/url_redirect.php?id=11154) ([file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#\\_1\\_.Criteria](https://grants.nih.gov/grants/guide/url_redirect.php?id=11154)). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

## **3. Anticipated Announcement and Award Dates**

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11123](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123)). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) ([https://grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)).

# **Section VI. Award Administration Information**

## **1. Award Notices**

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm) ([https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_2/2.5.1\\_just-in-time\\_procedures.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm)).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants](https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) ([https://grants.nih.gov/grants/policy/nihgps/HTML5/part\\_ii\\_subpart\\_b.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm)) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

## 2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/redirect.php?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/redirect.php?id=11157\)](https://grants.nih.gov/grants/guide/redirect.php?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(//grants.nih.gov/grants/guide/redirect.php?id=11159\)](https://grants.nih.gov/grants/guide/redirect.php?id=11159), including of note, but not limited to:

- [Federalwide Research Terms and Conditions \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_3/3.1\\_federalwide\\_standard\\_terms\\_and\\_conditions\\_for\\_research\\_grants.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- [Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-041.html)
- [Acknowledgment of Federal Funding \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4.2.1\\_acknowledgement\\_of\\_federal\\_funding.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>), and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- 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> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>), and <https://www.lep.gov> (<https://www.lep.gov>).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<https://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> (<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> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<https://www.hhs.gov/conscience/religious-freedom/index.html>).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other

information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

## Cooperative Agreement Terms and Conditions of Award

Not Applicable

## Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement \(/grants/policy/nihgps/HTML5/section\\_8/8.2.3\\_sharing\\_research\\_resources.htm#Data\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

## 3. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(/grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.4.1\\_reporting.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_8/8.6\\_closeout.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH FOAs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) ([/grants.nih.gov/grants/guide/url\\_redirect.php?id=11170](https://grants.nih.gov/grants/guide/url_redirect.php?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4.1.8\\_federal\\_funding\\_accountability\\_and\\_transparency\\_act\\_ffata\\_.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.8_federal_funding_accountability_and_transparency_act_ffata_.htm) for additional information on this reporting requirement.

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 from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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 FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

### Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: <http://grants.nih.gov/support/> ([/grants.nih.gov/support/](https://grants.nih.gov/support/)) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov) (<mailto:support@grants.gov>)

### Scientific/Research Contact(s)

Rosalind King, PhD  
Office of Behavioral and Social Sciences Research (OBSSR)  
Phone: 301-451-3832  
Email: [kingros@nih.gov](mailto:kingros@nih.gov) (<mailto:kingros@nih.gov>)

Sarika Parasuraman, PhD, MPH  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
Phone: 301-435-5482  
Email: [sarika.parasuraman@mail.nih.gov](mailto:sarika.parasuraman@mail.nih.gov) (<mailto:sarika.parasuraman@mail.nih.gov>)

Karen A. Kehl, PhD, RN  
National Institute of Nursing Research  
Telephone: 301-594-8010  
Email: [karen.kehl@nih.gov](mailto:karen.kehl@nih.gov) (<mailto:karen.kehl@nih.gov>)

Yan Wang, MD, PhD  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
Phone: 301-594-5032  
Email: [Yan.Wang1@nih.gov](mailto:Yan.Wang1@nih.gov) (<mailto:Yan.Wang1@nih.gov>)

Elizabeth Anne Barr, Ph.D.  
Office of Research on Women's Health (ORWH)  
Phone: 301-402-7895  
E-mail: [elizabeth.barr@nih.gov](mailto:elizabeth.barr@nih.gov) (<mailto:elizabeth.barr@nih.gov>)

Arielle Samantha Gillman  
National Institute on Minority Health and Health Disparities (NIMHD)  
Phone: 301-402-1366  
E-mail: [arielle.gillman@nih.gov](mailto:arielle.gillman@nih.gov) (<mailto:arielle.gillman@nih.gov>)

Layla Esposito, PhD  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)  
Telephone: 301-435-6888  
Email: [espositl@mail.nih.gov](mailto:espositl@mail.nih.gov) (<mailto:espositl@mail.nih.gov>)

Marsha Lopez  
National Institute on Drug Abuse (NIDA)  
Phone: 301-402-1846  
E-mail: [lopezmar@mail.nih.gov](mailto:lopezmar@mail.nih.gov) (<mailto:lopezmar@mail.nih.gov>)

Jill Reedy, PhD, MPH, RDN  
National Cancer Institute (NCI)  
Phone: 240-276-6812  
Email: [reedyj@mail.nih.gov](mailto:reedyj@mail.nih.gov) (<mailto:reedyj@mail.nih.gov>)

Bramaramba Kowtha MS, RDN, LDN  
Office of Disease Prevention (ODP)  
Telephone: 301-435-8052  
Email: [bramaramba.kowtha@nih.gov](mailto:bramaramba.kowtha@nih.gov)

### Peer Review Contact(s)

Center for Scientific Review (CSR)  
Email: [FOAReviewContact@csr.nih.gov](mailto:FOAReviewContact@csr.nih.gov) (<mailto:FOAReviewContact@csr.nih.gov>)

### Financial/Grants Management Contact(s)

The Office of Behavioral and Social Sciences Research (OBSSR (<https://obssr.od.nih.gov/>)) cannot accept assignments of applications or manage funded research projects. Please contact the IC-based grants management professionals below for related inquiries .

Judy Fox  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
Telephone: 301-443-4707  
Email: [jfox@mail.nih.gov](mailto:jfox@mail.nih.gov) (<mailto:jfox@mail.nih.gov>)

Ron Wertz  
National Institute of Nursing Research (NINR)  
Telephone: 301-594-2807  
Email: [wertzr@mail.nih.gov](mailto:wertzr@mail.nih.gov) (<mailto:wertzr@mail.nih.gov>)

Sahar Rais-Danai  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
Phone: 301-594-5032  
E-mail: [sahar.rais-danai@nih.gov](mailto:sahar.rais-danai@nih.gov) (<mailto:sahar.rais-danai@nih.gov>)

Priscilla Grant  
National Institute on Minority Health and Health Disparities (NIMHD)  
Phone: 301-594-8412  
E-mail: [pg38h@nih.gov](mailto:pg38h@nih.gov) (<mailto:pg38h@nih.gov>)

Margaret Young  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)  
Telephone: 301-642-4552  
Email: [margaret.young@nih.gov](mailto:margaret.young@nih.gov) (<mailto:margaret.young@nih.gov>)

Pamela G Fleming  
National Institute on Drug Abuse (NIDA)  
Phone: 301-480-1159  
E-mail: [pfleming@mail.nih.gov](mailto:pfleming@mail.nih.gov) (<mailto:pfleming@mail.nih.gov>)

Crystal Wolfrey  
National Cancer Institute (NCI)  
Phone: 240-276-6277  
Email: [crystal.wolfrey@nih.gov](mailto:crystal.wolfrey@nih.gov)

## Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) ([/grants.nih.gov/grants/guide/url\\_redirect.php?id=11163](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163)) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164) ([/grants.nih.gov/grants/guide/url\\_redirect.php?id=11164](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) ([/grants.nih.gov/grants/guide/url\\_redirect.php?id=11120](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120)).

### Authority and Regulations

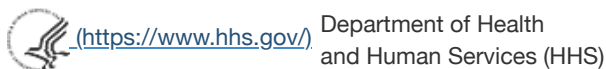
Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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[Weekly TOC for this Announcement](https://grants/guide/WeeklyIndex.cfm?09-02-22) ([/grants/guide/WeeklyIndex.cfm?09-02-22](https://grants/guide/WeeklyIndex.cfm?09-02-22))

[NIH Funding Opportunities and Notices](https://grants/guide/index.html) ([/grants/guide/index.html](https://grants/guide/index.html))

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NIH... Turning Discovery Into Health®

# EXHIBIT C



National Institutes of Health  
Office of Extramural Research

March 12, 2025

Cary Williams  
Harvard Pilgrim Health Care  
Email: [research\\_admin@hphci.harvard.edu](mailto:research_admin@hphci.harvard.edu)

Dear Cary Williams:

Funding for Project Number 1R61HD117134-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,<sup>1</sup> and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.<sup>2</sup>

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."<sup>3</sup>

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."<sup>4</sup> According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."<sup>5</sup> 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 program.

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,"<sup>6</sup> no corrective action is possible here. The premise of Project Number 5

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<sup>1</sup> <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

<sup>2</sup> 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

<sup>3</sup> *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

<sup>4</sup> 2024 Policy Statement at IIA-1.

<sup>5</sup> *Id.* at IIA-155.

<sup>6</sup> 2024 Policy Statement at IIA-156.

1R61HD117134-01 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.<sup>7</sup> 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*.<sup>8</sup>

### **Administrative Appeal**

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

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.<sup>11</sup>

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.<sup>12</sup>

Sincerely,

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

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<sup>7</sup> See 2 C.F.R. § 200.343 (2024).

<sup>8</sup> 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c).

<sup>9</sup> See 45 C.F.R. § 75.374.

<sup>10</sup> See 42 C.F.R. Part 50, Subpart D.

<sup>11</sup> *Id.* § 50.406(a).

<sup>12</sup> *Id.* § 50.406(b).

# EXHIBIT D



## Recipient Information

### 1. Recipient Name

HARVARD PILGRIM HEALTH CARE INC  
1 WELLNESS WAY  
CANTON, MA 02021

### 2. Congressional District of Recipient

08

### 3. Payment System Identifier (ID)

1042452600A1

### 4. Employer Identification Number (EIN)

042452600

### 5. Data Universal Numbering System (DUNS)

071721088

### 6. Recipient's Unique Entity Identifier

NZVVQ8GNVX65

### 7. Project Director or Principal Investigator

Brittany Michelle Charlton, DSC  
Assistant Professor  
bcharlton@mail.harvard.edu  
617-466-9262

### 8. Authorized Official

Cary Williams

## Federal Agency Information

### 9. Awarding Agency Contact Information

Yvonne C. Talley  
Grants Management Official  
EUNICE KENNEDY SHRIVER NATIONAL  
INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT  
talleyy@mail.nih.gov  
301-496-7432

### 10. Program Official Contact Information

Ronna Popkin  
  
EUNICE KENNEDY SHRIVER NATIONAL  
INSTITUTE OF CHILD HEALTH & HUMAN  
DEVELOPMENT  
ronna.popkin@nih.gov  
301-827-5121

## Federal Award Information

### 11. Award Number

1R61HD117134-01

### 12. Unique Federal Award Identification Number (FAIN)

R61HD117134

### 13. Statutory Authority

42 USC 241 42 CFR PART 52

### 14. Federal Award Project Title

Supportive and restrictive factors and mental health in LGBT adolescent and young adult populations

### 15. Assistance Listing Number

93.865

### 16. Assistance Listing Program Title

Child Health and Human Development Extramural Research

### 17. Award Action Type

New Competing (REVISED)

### 18. Is the Award R&D?

Yes

## Summary Federal Award Financial Information

### 19. Budget Period Start Date 08/26/2024 – End Date 03/12/2025

### 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

\$838,837

### 24. Total Approved Cost Sharing or Matching, where applicable

\$0

### 25. Total Federal and Non-Federal Approved this Budget Period

\$838,837

### 26. Project Period Start Date 08/26/2024 – End Date 03/12/2025

### 27. Total Amount of the Federal Award including Approved Cost

\$838,837

Sharing or Matching this Project Period

### 28. Authorized Treatment of Program Income

Additional Costs

### 29. Grants Management Officer - Signature

Margaret A. Young

## 30. Remarks

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



Phase 1 Exploratory/Developmental Grant  
Department of Health and Human Services  
National Institutes of Health

## Notice of Award



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

### SECTION I – AWARD DATA – 1R61HD117134-01 REVISED

**Principal Investigator(s):**

Brittany Michelle Charlton, DSC

**Award e-mailed to:** research\_admin@hphci.harvard.edu

Dear Authorized Official:

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

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R61HD117134. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	\$140,347
Fringe Benefits	\$41,823
Personnel Costs (Subtotal)	\$182,170
Consultant Services	\$5,000
Travel	\$6,500
Subawards/Consortium/Contractual Costs	\$500,845
 Federal Direct Costs	 \$694,515
Federal F&A Costs	\$144,322
Approved Budget	\$838,837
Total Amount of Federal Funds Authorized (Federal Share)	\$838,837
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$838,837</b>
 <b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	 <b>\$0</b>

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$838,837	\$838,837

**Fiscal Information:**

**Payment System Identifier:** 1042452600A1  
**Document Number:** RHD117134A  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2024

IC	CAN	2024
OD	8055729	\$838,837

**NIH Administrative Data:**

**PCC:** PDB -RP / **OC:** 41021 / **Released:** 03/14/2025

**Award Processed:** 03/15/2025 12:09:47 AM

**SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD117134-01 REVISED**

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

**SECTION III – STANDARD TERMS AND CONDITIONS – 1R61HD117134-01 REVISED**

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

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

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

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

research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

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) R61HD117134. 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](https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf). Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

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

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

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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

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

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

#### **Treatment of Program Income:**

Additional Costs

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#### **SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R61HD117134-01 REVISED**

Clinical Trial Indicator: No

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

**REVISION:** This revised award terminates the budget, and the project end dates to 03/12/2025.

It is the policy of NIH not to prioritize Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research

programs. Therefore, this project is terminated. HARVARD PILGRIM HEALTH CARE, INC., may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered.

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. Â§ 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.

Data Management and Sharing Policy: Applicable

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

#### SPREADSHEET SUMMARY

**AWARD NUMBER:** 1R61HD117134-01 REVISED

**INSTITUTION:** HARVARD PILGRIM HEALTH CARE

Budget	Year 1
Salaries and Wages	\$140,347
Fringe Benefits	\$41,823
Personnel Costs (Subtotal)	\$182,170
Consultant Services	\$5,000
Travel	\$6,500
Subawards/Consortium/Contractual Costs	\$500,845
TOTAL FEDERAL DC	\$694,515
TOTAL FEDERAL F&A	\$144,322
TOTAL COST	\$838,837

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	66%
F&A Cost Base 1	\$218,670
F&A Costs 1	\$144,322

# EXHIBIT E



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

**Notice of Award**  
FAIN# R01MD015256  
**Federal Award Date**  
05/16/2021

**Recipient Information****1. Recipient Name**

CHILDREN'S HOSPITAL CORPORATION, THE  
300 LONGWOOD AVE

BOSTON, MA 02115

**2. Congressional District of Recipient**  
07**3. Payment System Identifier (ID)**  
1042774441A1**4. Employer Identification Number (EIN)**  
042774441**5. Data Universal Numbering System (DUNS)**  
076593722**6. Recipient's Unique Entity Identifier****7. Project Director or Principal Investigator**

Brittany Michelle Charlton, DSC  
Assistant Professor  
bcharlton@mail.harvard.edu  
857-218-5463

**8. Authorized Official**  
Jamie Chan**Federal Agency Information****9. Awarding Agency Contact Information**

CARLA GRIFFITH  
Grants Management Specialist  
NATIONAL INSTITUTE ON MINORITY  
HEALTH AND HEALTH DISPARITIES  
griffithcp@mail.nih.gov  
301-594-8944

**10. Program Official Contact Information**

DOROTHY M CASTILLE  
Health Scientist Administrator  
NATIONAL INSTITUTE ON MINORITY  
HEALTH AND HEALTH DISPARITIES  
dorothy.castille@nih.gov  
301-594-9411

**Federal Award Information****11. Award Number**

1R01MD015256-01A1

**12. Unique Federal Award Identification Number (FAIN)**

R01MD015256

**13. Statutory Authority**

42 USC 241 42 CFR 52

**14. Federal Award Project Title**

Sexual orientation-related disparities in obstetrical and perinatal health

**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 05/16/2021 – End Date 02/28/2022**

**20. Total Amount of Federal Funds Obligated by this Action** \$929,389

20 a. Direct Cost Amount \$580,577

20 b. Indirect Cost Amount \$348,812

**21. Authorized Carryover** \$0

**22. Offset** \$0

**23. Total Amount of Federal Funds Obligated this budget period** \$929,389

**24. Total Approved Cost Sharing or Matching, where applicable** \$0

**25. Total Federal and Non-Federal Approved this Budget Period** \$929,389

**26. Project Period Start Date 05/16/2021 – End Date 02/28/2026**

**27. Total Amount of the Federal Award including Approved Cost  
Sharing or Matching this Project Period** \$929,389

**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.



RESEARCH  
Department of Health and Human Services  
National Institutes of Health



NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

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**SECTION I – AWARD DATA – 1R01MD015256-01A1**

**Principal Investigator(s):**

Brittany Michelle Charlton, DSC

**Award e-mailed to:** osp@childrens.harvard.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$929,389 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to BOSTON CHILDREN'S HOSPITAL 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 R01MD015256. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	\$261,108
Fringe Benefits	\$82,310
Personnel Costs (Subtotal)	\$349,418
Consultant Services	\$19,200
Materials & Supplies	\$1,000
Travel	\$7,500
Other	\$885
Subawards/Consortium/Contractual Costs	\$202,574

Federal Direct Costs	\$580,577
Federal F&A Costs	\$348,812
Approved Budget	\$929,389
Total Amount of Federal Funds Authorized (Federal Share)	\$929,389
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$929,389</b>
<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$929,389</b>

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$929,389	\$929,389
2	\$859,031	\$859,031
3	\$849,882	\$849,882
4	\$849,117	\$849,117
5	\$846,211	\$846,211

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

**Fiscal Information:**

Payment System Identifier: 1042774441A1  
Document Number: RMD015256A  
PMS Account Type: P (Subaccount)  
Fiscal Year: 2021

IC	CAN	2021	2022	2023	2024	2025
MD	8472687	\$929,389	\$859,031	\$849,882	\$849,117	\$846,211

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

**NIH Administrative Data:**

PCC: CPS01DC / OC: 41021 / Released: Grant, Priscilla 05/09/2021

Award Processed: 05/16/2021 08:13:51 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01MD015256-01A1**

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

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**SECTION III – STANDARD TERMS AND CONDITIONS – 1R01MD015256-01A1**

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:

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

- Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
  - f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS 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) R01MD015256. 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

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, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/20, 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 committed levels for future years reflect the removal of inflationary escalation.

**INFORMATION** In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. This award is issued with a 9.5 month budget period and with 12 months of support. Continuation awards will cycle each year on March 1st.

**INFORMATION:** Although the budget period start date for this award is May 16th, this award includes funds for 12 months of support. Future year budget periods will cycle on March 1st. Allowable preaward 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>

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

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

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

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

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

**INFORMATION:** See "Federalwide Assurance Requirements" and "Certification of IRB Approval" under the Human Subjects Protections section in the NIH Grants Policy Statement (NIHGPS), for specific requirements and recipient responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award. The NIHGPS can found on the internet at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

**INFORMATION:** Funds awarded for direct cost compensation for Graduate Research Assistants are limited in accordance with the NIH policy.

**INFORMATION** None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See the new Salary Limitations on Grants: [https://grants.nih.gov/grants/policy/salcap\\_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm)

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

**INFORMATION:** Regarding changes in scope, attention is called to the NIH Grants Policy Statement. The Change in Scope section is found in Section 8.1.2 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>. The recipient must obtain prior approval from the NIMHD for a change in the direction, aims, objectives, purposes, or type of research or training, or other areas that constitute a significant change in the approved project. Specific examples are provided.

**INFORMATION:** Regarding allowability of selected items of cost, attention is called to the NIH Grants Policy Statement. The Selected Items of Cost section is found in Section 7.9.1 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

**INFORMATION:** Honoraria are unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable. See Section 7.9.1 at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>.

**INFORMATION** This award includes funds awarded for consortium activity. Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH GPS is available at: <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>. See "Consortium Agreements" in Section 15 for specific responsibilities and requirements for recipients and consortium participants, which are applicable to and are a term and condition of this award.

**RESTRICTION:** Stipends and payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project (NIH GPS Section 7.9.1). Compensation must be in accordance with organizational policies consistently applied to both federally and non-federally supported activities and must be supported by acceptable accounting records that reflect the employer-employee relationship. Under these conditions, the funds provided as compensation for services rendered are not considered stipend supplementation; they are allowable charges to Federal grants, including PHS research grants. (A stipend is a payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.) See the NIH Grants Policy Statement for allowable forms of student compensation, available at <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

INSTITUTION: BOSTON CHILDREN'S HOSPITAL

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$267,108	\$262,190	\$258,026	\$251,047	\$252,126
Fringe Benefits	\$82,310	\$79,969	\$72,973	\$73,520	\$70,799
Personnel Costs (Subtotal)	\$349,418	\$342,159	\$330,999	\$324,567	\$322,925
Consultant Services	\$19,200	\$19,200	\$19,200	\$19,200	\$19,200
Materials & Supplies	\$1,000	\$1,000	\$1,000	\$1,000	\$1,000
Travel	\$7,500	\$7,500	\$7,500	\$9,500	\$9,500
Other	\$885	\$885	\$885	\$885	\$885
Subawards/Consortium/Contractual Costs	\$202,574	\$202,814	\$209,878	\$209,878	\$209,878
Publication Costs			\$2,000	\$6,000	\$6,000
TOTAL FEDERAL DC	\$580,577	\$573,558	\$571,462	\$571,030	\$569,388
TOTAL FEDERAL F&A	\$348,812	\$285,473	\$278,420	\$278,087	\$276,823
TOTAL COST	\$929,389	\$859,031	\$849,882	\$849,117	\$846,211

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	77%	77%	77%	77%	77%
F&A Cost Base 1	\$453,003	\$370,744	\$361,584	\$361,152	\$359,510
F&A Costs 1	\$348,812	\$285,473	\$278,420	\$278,087	\$276,823

# EXHIBIT F

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

Notice of Award

FAIN# R01MD015256  
Federal Award Date  
02/18/2025

Recipient Information

1. Recipient Name  
HARVARD PILGRIM HEALTH CARE INC  
1 WELLNESS WAY  
CANTON, MA 02021

2. Congressional District of Recipient  
08

3. Payment System Identifier (ID)  
1042452600A1

4. Employer Identification Number (EIN)  
042452600

5. Data Universal Numbering System (DUNS)  
071721088

6. Recipient's Unique Entity Identifier  
NZVVQ8GNVX65

7. Project Director or Principal Investigator  
Brittany Michelle Charlton, DSC  
Assistant Professor  
bcharlton@mail.harvard.edu  
617-466-9262

8. Authorized Official  
Charlotte Johnson  
research\_admin@harvardpilgrim.org

Federal Agency Information

9. Awarding Agency Contact Information  
MICHELLE MAE Phillips  
Grants Management Specialist  
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES  
michelle.phillips@nih.gov  
(301) 402-1366

10. Program Official Contact Information  
Priscah Mujuru  
Program Officer  
NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES  
priscah.mujuru@nih.gov  
301-594-9765

Federal Award Information

11. Award Number

5R01MD015256-05

12. Unique Federal Award Identification Number (FAIN)

R01MD015256

13. Statutory Authority

42 USC 241 42 CFR 52

14. Federal Award Project Title

Sexual orientation-related disparities in obstetrical and perinatal health

15. Assistance Listing Number

93.307

16. Assistance Listing Program Title

Minority Health and Health Disparities Research

17. Award Action Type

Non-Competing Continuation (REVISED)

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 03/01/2024 - End Date 04/30/2025

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

\$802,428

24. Total Approved Cost Sharing or Matching, where applicable

\$0

25. Total Federal and Non-Federal Approved this Budget Period

\$802,428

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26. Project Period Start Date 05/16/2021 - End Date 04/30/2026

27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period

\$3,917,674

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.

Page 1 of 6

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Notice of Award

RESEARCH

Department of Health and Human Services  
National Institutes of Health

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

SECTION I - AWARD DATA - 5R01MD015256-05 REVISED

Principal Investigator(s):  
Brittany Michelle Charlton, DSC

Award e-mailed to: [research\\_admin@hphci.harvard.edu](mailto:research_admin@hphci.harvard.edu)

Dear Authorized Official:

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

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. 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	\$246,010	
Fringe Benefits	\$68,883	
Personnel Costs (Subtotal)	\$314,893	
Travel	\$6,729	
Subawards/Consortium/Contractual Costs		\$260,235
Publication Costs	\$5,000	

Federal Direct Costs

\$586,857  
Federal F&A Costs  
\$215,571  
Approved Budget  
\$802,428  
Total Amount of Federal Funds Authorized (Federal Share)  
\$802,428  
TOTAL FEDERAL AWARD AMOUNT  
\$802,428

AMOUNT OF THIS ACTION (FEDERAL SHARE)  
\$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR ( 5 ) (for this Document Number)  
AWARD NUMBER  
TOTAL FEDERAL AWARD AMOUNT  
5R01MD015256-05  
\$802,428

3R01MD015256-05S1  
\$99,998

TOTAL  
\$902,426

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)  
YR  
THIS AWARD  
CUMULATIVE TOTALS

5  
\$802,428  
\$902,426

6  
\$801,979  
\$801,979

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

Fiscal Information:  
Payment System Identifier:  
1042452600A1  
Document Number:  
RMD015256B  
PMS Account Type:  
P (Subaccount)  
Fiscal Year:  
2024

IC

CAN  
2024  
2025  
MD  
8472687  
\$802,428  
\$801,979

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

NIH Administrative Data:  
PCC: CPS01PM / OC: 41025 / Released: 02/18/2025  
Award Processed: 02/19/2025 12:03:40 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01MD015256-05 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 - 5R01MD015256-05 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.

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) R01MD015256. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals,

see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm>.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

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

Treatment of Program Income:  
Additional Costs

#### SECTION IV - MD SPECIFIC AWARD CONDITIONS - 5R01MD015256-05 REVISED

Clinical Trial Indicator: No

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

INFORMATION: This revised award's end date has been adjusted to 4/30/25 due to the large unobligated balance.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 05/30/2024 ALSO APPLY TO THIS AWARD:

INFORMATION: This revised award has been issued in accordance with NIMHD's Fiscal Year 2024 funding policy for non-competing awards.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF AWARD LETTER ISSUED ON 02/03/2024 ALSO APPLY TO THIS AWARD:

REQUIREMENT: This award is subject to the conditions set forth in PA-20-185, NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed), NIH Guide to Grants and Contracts, 05/05/20, 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.

REQUIREMENT: The recipient is required to follow the data sharing plan included in the application and may not implement any changes in the plan without the written prior approval of the NIMHD.

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.

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

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

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

SPREADSHEET SUMMARY

AWARD NUMBER: 5R01MD015256-05 REVISED

INSTITUTION: HARVARD PILGRIM HEALTH CARE

Budget  
Year 5  
Year 6  
Salaries and Wages  
\$246,010  
\$246,010  
Fringe Benefits  
\$68,883  
\$68,883  
Personnel Costs (Subtotal)  
\$314,893  
\$314,893  
Travel  
\$6,729  
\$5,751  
Subawards/Consortium/Contractual Costs  
\$260,235  
\$261,410  
Publication Costs  
\$5,000  
\$5,000  
TOTAL FEDERAL DC  
\$586,857  
\$587,054  
TOTAL FEDERAL F&A  
\$215,571  
\$214,925  
TOTAL COST  
\$802,428  
\$801,979

Facilities and Administrative Costs  
Year 5  
Year 6  
F&A Cost Rate 1  
66%  
66%  
F&A Cost Base 1  
\$326,622  
\$325,644  
F&A Costs 1  
\$215,571  
\$214,925

Page 6 of 6

Version: 25 - 2/15/2024 9:51 AM | Generated on: 2/19/2025

12:03 AM

# EXHIBIT G

Fri, Mar 21, 2025 at 12:51 PM

Hi Brittany,

I'm sorry to forward the below termination notice for your R01.

Joe will be in contact with you to coordinate notification to subaward sites.

Cary

Cary Williams, MEd, CRA (she/her)

Director | Office of Sponsored Programs

Harvard Pilgrim Health Care, Inc. | Harvard Pilgrim Health Care Institute, LLC

617-867-4958 | [cary\\_williams@hphci.harvard.edu](mailto:cary_williams@hphci.harvard.edu)

Upcoming OOO: 3/27 – 4/4

From: Bulls, Michelle G. (NIH/OD) [E] <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

Sent: Friday, March 21, 2025 12:30 PM

To: Research Admin <[research\\_admin@hphci.harvard.edu](mailto:research_admin@hphci.harvard.edu)>

Subject: Grant Termination Notification

**WARNING:** This email originated from outside of the organization.  
Do not click links or attachments unless you recognize the sender and know the content is safe.



3/21/2025

Cary Williams

Harvard Pilgrim Health Care, Inc.

[research\\_admin@harvardpilgrim.org](mailto:research_admin@harvardpilgrim.org)

Dear Cary Williams:

Effective with the date of this letter, funding for Project Number 5R01MD015256-05 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,<sup>[1]</sup> and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.<sup>[2]</sup>

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

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.<sup>[4]</sup>" According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.<sup>[5]</sup>" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"<sup>[6]</sup> 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.<sup>[7]</sup> 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*.<sup>[8]</sup>

#### Administrative Appeal

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

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.<sup>[11]</sup>

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.<sup>[12]</sup>

Sincerely,

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

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

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

<sup>[2]</sup> 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

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

<sup>[4]</sup> NIH Grants Policy Statement at IIA-1.

<sup>[5]</sup> *Id.* at IIA-155.

<sup>[6]</sup> NIH Grants Policy Statement at IIA-156.

<sup>[7]</sup> See 2 C.F.R. § 200.343 (2024).

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

<sup>[9]</sup> See 45 C.F.R. § 75.374.

<sup>[10]</sup> See 42 C.F.R. Part 50, Subpart D

<sup>[11]</sup> 11 *Id.* § 50.406(a)

<sup>[12]</sup> 12 *Id.* § 50.406(b)

# EXHIBIT H

## Sexual and Gender Minority Populations in NIH-Supported Research

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Notice Number: NOT-OD-19-139

### Key Dates

**Release Date:** August 28, 2019

### Related Announcements

- **September 6, 2024** - Updating the Definition of Sexual and Gender Minority Populations in NIH-Supported Research. See Notice [NOT-OD-24-169](#).

### Issued by

Sexual and Gender Minority Research Office ([SGMRO](#))

### Purpose

The purpose of this Notice is to announce the revision of the definition of sexual and gender minority (SGM) populations for research purposes at the NIH, as well as to provide a summary of information about SGM health research at the NIH. It is expected that this Notice will help to enhance the representation of SGM individuals in the agency's research portfolio and to stimulate the development of novel research projects and strategies to better understand and advance SGM health.

### Implementation Timeline

This Notice is effective upon its release date.

### The Sexual & Gender Minority Research Office

The [NIH Fiscal Years 2016-2020 Strategic Plan to Advance Research on the Health and Well-Being of Sexual and Gender Minorities](#) was released in 2015. The plan elucidated goals and objectives to encourage the advancement of basic, clinical, behavioral, population, and social sciences research to improve the health of SGM individuals. One of the objectives of the strategic plan was to establish a central office to coordinate SGM-related research and activities at the NIH. Established in 2015, the [Sexual & Gender Minority Research Office](#) (SGMRO) resides within the [Division of Program Coordination, Planning, and Strategic Initiatives](#) (DPCPSI) in the NIH Office of the Director.

The NIH laid out four overarching goals in its FY 2016-2020 SGM strategic plan: (1) Expand the knowledge base of SGM health and well-being through NIH-supported research; (2) Remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being; (3) Strengthen the community of researchers and scholars who conduct research relevant to SGM health and well-being; and (4) Evaluate progress on advancing SGM research. The SGMRO pursues these goals by convening and participating in events involving SGM health priorities, managing dissemination of information about SGM health research, and working with NIH Institutes, Centers, and Offices (ICOs) to leverage resources and develop initiatives to promote SGM health and research.

### Definition of Sexual and Gender Minorities

At the NIH, the term sexual and gender minority originally encompassed individuals who identify as lesbian, gay, bisexual, transgender, queer, or intersex, as well as those who do not self-identify with one of these terms, but whose sexual orientation, gender identity, or reproductive development varies from traditional, societal, cultural, or physiological norms. The NIH has heretofore opted to use this definition to maintain inclusivity and consistency in reporting. However, after consultation with several NIH groups that possess contemporary expertise in SGM health and research, the NIH is releasing an updated SGM definition to foster and expand

inclusion of SGM individuals in health research by better clarifying the populations who fall under the SGM umbrella. The definition of SGM is revised to read as follows:

*SGM populations include, but are not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, Two-Spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.*

The SGMRO would like to make clear that this change in definition is not intended to exclude any person or population previously included under the former definition of SGM populations.

## **SGM as a Health Disparity Population**

SGM individuals face unique health challenges, and a continually growing body of evidence suggests that SGM individuals suffer disproportionately from a variety of conditions and diseases. In October 2016, the [National Institute on Minority Health and Health Disparities](#) (NIMHD), in collaboration with the [Agency for Healthcare Research and Quality](#) (AHRQ), [announced](#) that SGM populations had been officially designated as a health disparity population for NIH and AHRQ research. This designation has since facilitated the creation of tailored research projects, programs, and activities intended to tackle the distinct issues encountered by SGM individuals. In addition, ascertainment of SGM status in ongoing and planned population studies has been enhanced. However, SGM-specific health disparities persist today, and novel methods to measure, address, and prevent them are still needed.

## **Addressing SGM-Specific Health Disparities**

To help eliminate these disparities, the [21st Century Cures Act](#), which authorized funding to accelerate research in several key public health areas at the NIH, included provisions specifically intended to increase participation of SGM populations in NIH-supported clinical research and to facilitate the development of methods for conducting SGM research. In support of this, the NIH SGM Research Working Group (SGM RWG), a working group of the NIH [Council of Councils](#), recommended in its 2019 [Mid-Course Strategic Plan Review](#) that the NIH encourage applicants for clinical research funding to demonstrate consideration of inclusion of SGM populations whenever appropriate. Increased data collection and analyses on SGM populations may help to illuminate important information needed to address the health of these communities.

## **Inquiries**

Please direct all inquiries to:

Karen L Parker, PhD, MSW  
Division of Program Coordination, Planning, and Strategic Initiatives  
Sexual & Gender Minority Research Office  
Telephone: 301-451-2055?  
Email: [klparker@mail.nih.gov](mailto:klparker@mail.nih.gov)

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[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)

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# EXHIBIT I



#### Recipient Information

##### 1. Recipient Name

HARVARD PILGRIM HEALTH CARE INC  
1 WELLNESS WAY  
CANTON, MA 02021

##### 2. Congressional District of Recipient

08

##### 3. Payment System Identifier (ID)

1042452600A1

##### 4. Employer Identification Number (EIN)

042452600

##### 5. Data Universal Numbering System (DUNS)

071721088

##### 6. Recipient's Unique Entity Identifier

NZVVQ8GNVX65

##### 7. Project Director or Principal Investigator

Brittany Michelle Charlton, DSC  
Assistant Professor  
bcharlton@mail.harvard.edu  
617-466-9262

##### 8. Authorized Official

Charlotte Johnson  
research\_admin@harvardpilgrim.org

#### Federal Agency Information

##### 9. Awarding Agency Contact Information

MICHELLE MAE Phillips  
Grants Management Specialist  
NATIONAL INSTITUTE ON MINORITY  
HEALTH AND HEALTH DISPARITIES  
michelle.phillips@nih.gov  
(301) 402-1366

##### 10. Program Official Contact Information

Priscah Mujuru  
Program Officer  
NATIONAL INSTITUTE ON MINORITY  
HEALTH AND HEALTH DISPARITIES  
priscah.mujuru@nih.gov  
301-594-9765

#### Federal Award Information

##### 11. Award Number

3R01MD015256-05S1

##### 12. Unique Federal Award Identification Number (FAIN)

R01MD015256

##### 13. Statutory Authority

42 USC 241 42 CFR 52

##### 14. Federal Award Project Title

Improving service delivery models of medically assisted reproduction: A patient journey mapping study of sexual minority women couples' experience of medicalized family formation

##### 15. Assistance Listing Number

93.307

##### 16. Assistance Listing Program Title

Minority Health and Health Disparities Research

##### 17. Award Action Type

Supplement

##### 18. Is the Award R&D?

Yes

#### Summary Federal Award Financial Information

##### 19. Budget Period Start Date 03/01/2024 – End Date 02/28/2025

##### 20. Total Amount of Federal Funds Obligated by this Action

\$99,998

20 a. Direct Cost Amount

\$60,240

20 b. Indirect Cost Amount

\$39,758

##### 21. Authorized Carryover

##### 22. Offset

##### 23. Total Amount of Federal Funds Obligated this budget period

\$99,998

##### 24. Total Approved Cost Sharing or Matching, where applicable

\$0

##### 25. Total Federal and Non-Federal Approved this Budget Period

\$99,998

##### 26. Project Period Start Date 05/16/2021 – End Date 02/28/2026

##### 27. Total Amount of the Federal Award including Approved Cost

\$3,917,674

Sharing or Matching this Project Period

##### 28. Authorized Treatment of Program Income

Other (See Remarks)

##### 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.

**RESEARCH**

Department of Health and Human Services  
National Institutes of Health

## Notice of Award



NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

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**SECTION I – AWARD DATA – 3R01MD015256-05S1**
**Principal Investigator(s):**

Brittany Michelle Charlton, DSC

**Award e-mailed to:** research\_admin@harvardpilgrim.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$99,998 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to HARVARD PILGRIM HEALTH CARE in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute On Minority Health And Health Disparities of the National Institutes of Health under Award Number R01MD015256. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	\$44,753
Fringe Benefits	\$13,337
Personnel Costs (Subtotal)	\$58,090
Other	\$2,150
<b>Federal Direct Costs</b>	<b>\$60,240</b>
<b>Federal F&amp;A Costs</b>	<b>\$39,758</b>
<b>Approved Budget</b>	<b>\$99,998</b>
<b>Total Amount of Federal Funds Authorized (Federal Share)</b>	<b>\$99,998</b>
<b>TOTAL FEDERAL AWARD AMOUNT</b>	<b>\$99,998</b>
<b>AMOUNT OF THIS ACTION (FEDERAL SHARE)</b>	<b>\$99,998</b>

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR ( 5 ) (for this Document Number)	
AWARD NUMBER	TOTAL FEDERAL AWARD AMOUNT
3R01MD015256-05S1	\$99,998
5R01MD015256-05	\$802,428
<b>TOTAL</b>	<b>\$902,426</b>

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
5	\$99,998	\$902,426
6	\$0	\$801,979

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

**Fiscal Information:**

**Payment System Identifier:** 1042452600A1  
**Document Number:** RMD015256B  
**PMS Account Type:** P (Subaccount)  
**Fiscal Year:** 2024

IC	CAN	2024
OD	8025139	\$49,998
OD	8055775	\$50,000

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

**NIH Administrative Data:**

**PCC:** CPS01PM / **OC:** 41023 / **Released:** 09/03/2024

**Award Processed:** 09/04/2024 12:34:35 AM

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**SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01MD015256-05S1**

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

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**SECTION III – STANDARD TERMS AND CONDITIONS – 3R01MD015256-05S1**

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

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

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

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

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) R01MD015256. 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 is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

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

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>. For information about NIH's commitment to supporting a safe and respectful work environment,

who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see

<https://grants.nih.gov/grants/policy/harassment.htm>.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

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

#### **Treatment of Program Income:**

Other (See Remarks)

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#### **SECTION IV – MD SPECIFIC AWARD CONDITIONS – 3R01MD015256-05S1**

Clinical Trial Indicator: No

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

**RESTRICTION:** This supplemental award provides \$50,000 funding from the NIH Office of Research on Women's Health (ORWH) and \$49,998 from the Sexual and Gender Minority Research Office (SGMRO): These funds are restricted for this purpose and may not be expended for any other purpose without the written prior approval of the National Institute on Minority Health and Health Disparities.

**REQUIREMENT:** This award is subject to the conditions set forth in NOT-OD-22-032 and PA-20-272, Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional), NIH Guide to Grants and Contracts, 10/09/2020, which are 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.

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

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects at any site engaged in such research for any period not covered by both (1) the awardee's OHRP-approved Assurance

and if performance sites are involved, each performance site's OHRP approved Assurance(s) and (2) appropriate IRB approvals consistent with all OHRP approved Assurances.

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

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

#### **SPREADSHEET SUMMARY**

**AWARD NUMBER:** 3R01MD015256-05S1

**INSTITUTION:** HARVARD PILGRIM HEALTH CARE

Budget	Year 5	Year 6
Salaries and Wages	\$44,753	
Fringe Benefits	\$13,337	
Personnel Costs (Subtotal)	\$58,090	
Other	\$2,150	
TOTAL FEDERAL DC	\$60,240	
TOTAL FEDERAL F&A	\$39,758	
TOTAL COST	\$99,998	\$0

Facilities and Administrative Costs	Year 5	Year 6
F&A Cost Rate 1	66%	
F&A Cost Base 1	\$60,240	
F&A Costs 1	\$39,758	

# EXHIBIT J

This notice has expired. Check the **NIH Guide** for active opportunities and notices.

Notice of Special Interest (NOSI): Administrative Supplements for Research on Sexual and Gender Minority (SGM) Populations (Admin Supp Clinical Trial Optional)

Notice Number:  
NOT-OD-22-032

## Key Dates

Release Date:

December 2, 2021

First Available Due Date:

January 31, 2022

Expiration Date:

February 01, 2024

## Related Announcements

[NOT-MD-22-007](#) - Notice of National Institute on Minority Health and Health Disparities (NIMHD) Participation in NOT-OD-22-032, NOSI: Administrative Supplements for Research on Sexual and Gender Minority Populations (Admin Supp Clinical Trial Optional)

[PA-20-272](#) Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

## Issued by

Sexual and Gender Minority Research Office ([SCMRO](#))

National Human Genome Research Institute ([NHGRI](#))

National Institute on Aging ([NIA](#))

National Institute of Allergy and Infectious Diseases ([NIAID](#))

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](#))

National Institute on Deafness and Other Communication Disorders ([NIDCD](#))

National Institute of Dental and Craniofacial Research ([NIDCR](#))

National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK](#))

National Institute on Drug Abuse ([NIDA](#))

National Institute of Mental Health ([NIMH](#))

National Institute of Neurological Disorders and Stroke ([NINDS](#))

National Institute of Nursing Research ([NINR](#))

Fogarty International Center ([FIC](#))

National Center for Complementary and Integrative Health ([NCCIH](#))

National Cancer Institute ([NCI](#))

National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of AIDS Research ([OAR](#))

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention ([ODP](#))

Office of Research on Women's Health ([ORWH](#))

## Purpose

The mission of the NIH is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH is committed to supporting research that will increase scientific understanding of the health and well-being of various population and subpopulation groups and that will help to establish the effectiveness of evidence-based health interventions and services for individuals within these groups. NIH places high priority on research with populations that have distinct health risk profiles and who have also received insufficient attention from the scientific research enterprise. To this end, this Notice of Special Interest (NOSI) announces the availability of administrative supplements to provide funding for the expansion of existing research projects to incorporate sexual and gender minority (SGM) populations or SGM-relevant research questions. SGM populations include, but are not limited to, those populations described in [NOT-OD-19-139](#). Basic, social, behavioral, clinical, translational, and health services research relevant to the missions of the sponsoring NIH Institutes or Centers (ICs) may be proposed in response to this solicitation. Potential applicants are encouraged to review the most recent annual [Portfolio Analysis](#) of NIH-funded SGM research to identify potential research gaps that may be relevant to this NOSI. More information about the SGM administrative supplements program and previously awarded research projects can be found on the SGMRO [website](#).

## Background

The collective knowledge base on SGM health has grown substantially since the release of the groundbreaking 2011 Institute of Medicine (now the National Academy of Medicine) [report](#) on the health of lesbian, gay, bisexual, and transgender people. However, in their comprehensive 2020 [report](#) on the status and well-being of people who identify as SGM, the National Academies Committee on Population ultimately concluded that SGMs still face numerous disparities across multiple domains of well-being. In October 2016, the [National Institute on Minority Health and Health Disparities](#), in collaboration with the [Agency for Healthcare Research and Quality](#), [announced](#) that SGMs had been officially designated a health disparity population for NIH research purposes. This designation has facilitated the creation of tailored research projects, programs, activities, and funding opportunities to tackle the unique health-related issues encountered by SGM individuals. In addition, ascertainment of SGM status in ongoing and planned population studies has been enhanced. However, it is apparent that SGM-specific health disparities persist today, and there is still an urgent need for novel strategies to understand, measure, address, and prevent them.

As of August 28, 2019, the NIH definition of "sexual and gender minorities" includes, but is not limited to, individuals who identify as lesbian, gay, bisexual, asexual, transgender, two-spirit, queer, and/or intersex. Individuals with same-sex or -gender attractions or behaviors and those with a difference in sex development are also included. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex. Applicants to this administrative supplement may propose to study relevant SGM subpopulations not explicitly identified in this definition and/or adopt other classification frameworks and terminologies as appropriate.

## Specific Areas of Research Interest

This NOSI calls for research that will enrich scientific understanding of how sexual orientation, gender identity, and/or being born with differences/disorders in sex development (DSDs) or intersex characteristics relate to health outcomes, health risks, health behaviors, perceptions and expectations about health, and access to health-related services or associated barriers.

Appropriate topics or studies for these supplements may include, but are not limited to, those listed below:

- Addition of SGM participants to an ongoing study which either did not originally include them or has not enrolled enough SGM participants to make meaningful comparisons between groups; proposed studies must be sufficiently powered to allow for meaningful comparisons
- Expansion of an ongoing study focused on one SGM group to add another; proposed studies must be sufficiently powered to allow for meaningful comparisons
- Expansion of data collection (e.g., in surveys, questionnaires, etc.) to add items related to sexual attraction, sexual behavior, sexual identity, gender identity, gender expression, and/or non-binary sex when relevant and appropriate
- Secondary analyses of existing data to generate new information or hypotheses about SGM health
- Assessment of reliability and/or validity of measures relevant to sexual attraction, sexual behavior, sexual identity, gender identity, gender expression, and/or non-binary sex
- Methodological and strategic innovations to improve the recruitment and retention of SGM individuals in any research activity
- Expansion of prevention, screening, and wellness research tailored to SGM populations that aims to reduce health inequities
- Ethical, legal, or social science research on the implications of data collection and/or research findings on SGM populations

## Scope of Support

Administrative supplements can be used to meet increased costs that are within the scope of the approved parent award, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted. Applicants to this NOSI should propose research that, if successful, would contribute to a greater understanding of the health and well-being of SGM communities. Clinical trials cannot be proposed to be added to grants that do not include a clinical trial as that would constitute a change in scope.

## IC-Specific Considerations

All applications submitted in response to this NOSI should fall within the mission of the IC of the awarded parent grant. Applicants are strongly encouraged to discuss their proposed supplement project with the IC Program Officer of the funded parent award prior to submission of a supplement application in order to ensure that the proposed activity aligns with the scientific priorities of the IC and is within the scope of the parent award. Scientific inquiries may also be addressed to the contacts listed in the Inquiries section below.

## Other Information

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

## Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Please recognize that all SGM administrative supplement awards are made specifically for conducting the research proposed in each application. Progress reports specific to the SGM administrative supplement may be requested by SGMRO at any point. These progress report requests will be sent under separate cover from the Research Performance Progress Report. Unsatisfactory progress or reallocation of supplement funds to another purpose outside of the proposed research plan may lead to disqualification of participating programs from future consideration for this opportunity.

## Application and Submission Information

Applications for this initiative must be submitted using the following opportunity or its subsequent reissued equivalent.

- [PA-20-272](#) - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)

All instructions in the [SF424 \(R&R\) Application Guide](#) and [PA-20-272](#) must be followed, with the following additions:

- Application Due Dates January 31, 2022 for FY 2022; January 31, 2023 for FY 2023; and January 31, 2024 for FY 2024, by 5:00 PM local time of applicant organization.
- The expiration date is February 1, 2024.

- The project and budget periods must be within the currently approved project period for the existing parent award.
- For funding consideration, applicants must include **NOT-OD-22-032** (without quotation marks) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form. Applications without this information in box 4B will not be considered for this initiative.
- Requests may be for one year of support only.
- The project budget cannot exceed \$100,000 in total costs.
- The Research Strategy section of the application is limited to 6 pages.
- The process for Streamlined Submissions using the eRA Commons cannot be used for this initiative.
- Applicants are strongly encouraged to notify the Program Officer at the IC supporting the parent award that a request has been submitted in response to this NOSI in order to facilitate efficient processing of the application.

Applications that do not comply with these instructions or are deemed otherwise non-responsive to the terms of this NOSI, will not be accepted for review.

## Inquiries

Please direct all inquiries to the Program Officer associated with the parent award and/or the designated contact at the ICO supporting the parent award listed below:

### Scientific/Research Contact(s)

Brad Newsome, PhD  
Fogarty International Center (FIC)  
Telephone: 301-496-1653  
Email: [brad.newsome@nih.gov](mailto:brad.newsome@nih.gov)

Inna Belfer, MD, PhD  
National Center for Complementary and Integrative Health (NCCIH)  
Telephone: 301-435-1573  
Email: [inna.belfer@nih.gov](mailto:inna.belfer@nih.gov)

Whitney Barfield, PhD  
National Cancer Institute (NCI)  
Telephone: 240-276-6170  
Email: [whitney.barfield@nih.gov](mailto:whitney.barfield@nih.gov)

Tina L Gatlin, PhD  
National Human Genome Research Institute (NHGRI)  
Telephone: 301-480-2280  
Email: [gatlincl@mail.nih.gov](mailto:gatlincl@mail.nih.gov)

Melissa Gerald, PhD  
National Institute on Aging (NIA)  
Telephone: 301-496-3136  
Email: [melissa.gerald@nih.gov](mailto:melissa.gerald@nih.gov)

Keith Crawford, PhD  
National Institute of Allergy and Infectious Diseases (NIAID)  
Telephone: 240-669-2816  
Email: [keith.crawford@nih.gov](mailto:keith.crawford@nih.gov)

Heiyoung Park, PhD  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
Telephone: 301-594-5032  
Email: [parkh1@mail.nih.gov](mailto:parkh1@mail.nih.gov)

Richard A Jenkins, PhD  
National Institute on Drug Abuse (NIDA)  
Telephone: 301-443-6504  
Email: [jenkinsri@mail.nih.gov](mailto:jenkinsri@mail.nih.gov)

Carol B Hubner, PhD  
National Institute on Drug Abuse (NIDA)  
Telephone: 301-827-5926  
Email: [chubner@nida.nih.gov](mailto:chubner@nida.nih.gov)

Janet Cyr, PhD  
National Institute on Deafness and Other Communication Disorders (NIDCD)  
Telephone: 301-402-3458  
Email: [cyrj@nidcd.nih.gov](mailto:cyrj@nidcd.nih.gov)

Dena Fischer, DDS, MSD, MS  
National Institute of Dental & Craniofacial Research (NIDCR)  
Telephone: 301-594-4876  
Email: [dena.fischer@nih.gov](mailto:dena.fischer@nih.gov)

Vanessa A White, MPH  
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)  
Telephone: 301-827-5505  
Email: [vanessa.white@nih.gov](mailto:vanessa.white@nih.gov)

Beshaun Davis, Ph.D.  
National Institute of Mental Health (NIMH)  
Telephone: 301-827-5098  
Email: [beshaun.davis@nih.gov](mailto:beshaun.davis@nih.gov)

Erica Littlejohn, PhD  
National Institute of Neurological Disorders and Stroke (NINDS)  
Telephone: 301-435-2719  
Email: [Erica.Littlejohn@nih.gov](mailto:Erica.Littlejohn@nih.gov)

Shalanda A Bynum, PhD, MPH  
National Institute of Nursing Research (NINR)  
Email: [shalanda.bynum@nih.gov](mailto:shalanda.bynum@nih.gov)

Elizabeth L Neilson, PhD, MPH, MSN  
Office of Disease Prevention (ODP)  
Telephone: 301-827-5578  
Email: [Elizabeth.Neilson@nih.gov](mailto:Elizabeth.Neilson@nih.gov)

Elizabeth Anne Barr, PhD  
Office of Research on Women's Health (ORWH)  
Telephone: 301-402-7895  
Email: [elizabeth.barr@nih.gov](mailto:elizabeth.barr@nih.gov)

Melissa Mera, MPH  
Office of AIDS Research (OAR)  
Telephone: 301-761-7689  
Email: [melissa.mera@nih.gov](mailto:melissa.mera@nih.gov)

Robert Freeman PhD  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
Telephone: 301-443 8820  
Email: [Robert.Freeman@nih.gov](mailto:Robert.Freeman@nih.gov)

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[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)

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# EXHIBIT K

Fri, Mar 21, 2025 at 3:56 PM

Hi Brittany,

As you noted, the terminations continue. The supplement associated with the R01 has also been terminated.

Cary

**Cary Williams, MEd, CRA** (she/her)

Director | Office of Sponsored Programs

Harvard Pilgrim Health Care, Inc. | Harvard Pilgrim Health Care Institute, LLC

617-867-4958 | [cary\\_williams@hphci.harvard.edu](mailto:cary_williams@hphci.harvard.edu)

Upcoming OOO: 3/27 – 4/4

**From:** Bulls, Michelle G. (NIH/OD) [E] <[michelle.bulls@nih.gov](mailto:michelle.bulls@nih.gov)>

**Sent:** Friday, March 21, 2025 12:35 PM

**To:** Research Admin <[research\\_admin@hphci.harvard.edu](mailto:research_admin@hphci.harvard.edu)>

**Subject:** Grant Termination Notification

**WARNING:** This email originated from outside of the organization.  
Do not click links or attachments unless you recognize the sender and know the content is safe.



3/21/2025

Cary Williams

Harvard Pilgrim Health Care, Inc.

[research\\_admin@harvardpilgrim.org](mailto:research_admin@harvardpilgrim.org)

Dear Cary Williams:

Effective with the date of this letter, funding for Project Number 3R01MD015256-05S1 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,<sup>[1]</sup> and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.<sup>[2]</sup>

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

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.<sup>[4]</sup>" According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.<sup>[5]</sup>" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

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

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"<sup>[6]</sup> 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.<sup>[7]</sup> 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*.<sup>[8]</sup>

#### Administrative Appeal

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

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.<sup>[11]</sup>

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.<sup>[12]</sup>

Sincerely,

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

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

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

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

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

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

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

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

[7] See 2 C.F.R. § 200.343 (2024).

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

[9] See 45 C.F.R. § 75.374.

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

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)