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

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

Plaintiffs,

v.

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

Defendants.

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

**DECLARATION OF
HEIDI MOSESON**

* Application for *Pro Hac Vice* Admission Forthcoming

** Out-of-State Licensee Renewal Pending

(Additional Counsel on Behalf of Plaintiffs)

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FOUNDATION OF NORTHERN CALIFORNIA**

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* Application for *Pro Hac Vice* Admission Forthcoming

1 I, Heidi Moseson, declare:

2 1. My name is Heidi Moseson.

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

5 3. I am an Epidemiologist and Senior Research Scientist at Ibis Reproductive Health
6 (“Ibis”) in Oakland, California. I have extensive experience in clinical and social science research and
7 have led a clinical trial, National Institutes of Health (“NIH”) funded studies as Principal Investigator
8 (“PI”), and other quantitative and qualitative research for more than 15 years. Ibis is a global research
9 organization whose mission is to drive change through bold, rigorous research and principled
10 partnerships that advance sexual and reproductive autonomy, choices, and health worldwide. I have been
11 a Senior Research Scientist at Ibis since 2020, and previously served as an Associate at Ibis.

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

14 5. As a Senior Research Scientist, I lead grant-writing, study design, implementation,
15 statistical analysis, and dissemination for research on abortion, contraception, gender-affirming care, and
16 family building. I design and lead research that identifies barriers and facilitators to reproductive health
17 care, particularly abortion and contraception, in the context of shifting policies in the United States. I
18 also lead research on the safety and effectiveness of various models of medication abortion care
19 (abortion with pills), including an ongoing randomized clinical trial in the United States. Additionally, I
20 design and lead research on the family planning needs and experiences of sexual and gender minority
21 people, including development of survey methods and other research measures that are more accurate
22 for sexual and reproductive health experiences. Public health research is core to my and Ibis’s work,
23 which is informed by relationships and collaboration with community partners, including organizations
24 and individuals representing pregnant people seeking abortion care and transgender and gender diverse
25 community members, to identify key gaps in information and resources concerning reproductive health,
26 autonomy, and health care access for these populations.

27 6. I earned a PhD in Epidemiology & Translational Science from the University of
28 California, San Francisco, a Masters of Public Health in Epidemiology & Biostatistics from the

1 University of California, Berkeley, and a Bachelor of Arts in International Relations & Human Biology
2 from Stanford University.

3 7. I am widely published in top journals in my field, including in *Lancet*, *Journal of the*
4 *National Cancer Institute*, *New England Journal of Medicine*, *American Journal of Epidemiology*,
5 *American Journal of Public Health*, *JAMA Network Open*, *Contraception*, and *Perspectives in Sexual*
6 *and Reproductive Health*, among many others.

7 8. I am the recipient of numerous honors, including the Vittinghoff Innovation Award for
8 Methodological Innovation and Excellence from the University of California, San Francisco, the
9 Outstanding Young Investigator Award from the North American Forum on Family Planning, and the
10 Soroptimist Award for Women in Science.

11 9. I have been funded on multiple NIH awards as a PI, and my research has also been
12 funded through grants from the American College of Obstetrics and Gynecology (ACOG) Foundation,
13 the Society of Family Planning, the David & Lucile Packard Foundation, among others organizations.

14 10. The process for applying for an NIH grant is laborious and preparation of the application
15 can take years and almost universally requires extensive evening and weekend hours. I first began
16 preparation for the grant at issue in September 2022, and it took 13 months from that point to draft the
17 full grant application which we submitted on October 31, 2024. To develop the grant application, we
18 had to have a full study design in place with contingencies, a detailed budget projected over five years,
19 and letters of support from over a dozen community partners who pledged to work with us on the
20 grant—with funding agreements worked out in advance for each of them as well. This experience is
21 consistent with typical NIH application development, which involves conceptualization, relationship
22 building, study design, drafting, multiple expert consultation, and an iterative process of review and
23 revision. Proposals often exceed 200 pages and must make a compelling case that the health issue being
24 studied is urgent and scientifically significant. As applicants, we must prove that our proposed methods
25 are the best possible approach to address the research question. We must also demonstrate that our team
26 is uniquely qualified to achieve the proposed aims. Every application undergoes rigorous peer review by
27 experts, and funding rates are low.

11. Ibis is a plaintiff in the lawsuit *American Public Health Association v. National Institutes of Health*, No. 1:25-cv-10787 (D. Mass.). In March 2025, NIH terminated two grants on which I served as the PI, a research grant entitled “*Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality*” and a grant providing supplemental funding for that award. Both terminations were vacated as a result of that lawsuit. The grant discussed in this declaration is separate from the grants that were at issue in that lawsuit.

12. I am currently a Multiple PI (“MPI”) on an NIH grant from the National Institute of Child Health and Human Development (“NICHD”) entitled “*Time Sensitive Research on Barriers to Pregnancy Care*.” Under an MPI model, two or more individuals are listed as co-equal PIs on a grant, with equal scientific authority, fiscal accountability, and administrative responsibility for the project. I conceptualized, designed, and drafted this grant application with my MPI at Indiana University. We pursued this model because we recognized that the research project’s success hinges upon the blend of distinct and complementary epidemiological and clinical expertise and experience that we bring. Further, we had a history of co-leadership of research in the Midwest on abortion access that prepared us well for this next study.

13. The primary institutional grantee for the award is Indiana University, and Ibis is a sub-awardee. Institutional grantees are the entities that host the research and receive the NIH award and funding, and are generally universities, hospitals, and sometimes non-profits and other entities. Awards also name one or more PIs, who are researchers directly responsible for proposing the projects, overseeing the design and implementation of studies, and managing the research from the application stage through the end of a grant. Under this arrangement, Indiana University transfers a pre-specified amount of the award to Ibis for research staff time, participant remuneration, and other costs detailed in the NIH-reviewed grant application. On a day-to-day basis, I work closely with my MPI at Indiana University through weekly meetings with the full team, as well as multiple 1:1 meetings between the two of us to move the work forward. We work closely together, with frequent communication—similar to if we were at the same institution.

14. The grant number was originally funded as a one-year research project under grant number R61HD116143, with a project term of August 20, 2024–July 31, 2025.

1 15. Attached hereto as **Exhibit 1** is a true and correct copy of the R61 grant's Notice of
2 Award (i.e., "NOA").

3 16. The R61 mechanism is a bi-phased grant award that is milestone-driven, and combines
4 two distinct phases of funding into a single application and review cycle to accelerate time sensitive
5 research. The initial R61 phase lasts for 12 months, and if the milestones are successfully met and funds
6 are available, the grant transitions to the R33 phase for an additional four years. The specific call for
7 proposals under which this grant was awarded was PAR-22-233 that aimed to fund research designed to
8 evaluate the impact of unexpected or sudden legal/policy changes, large-scale infrastructure shifts, or
9 major environmental/public health events.

10 17. The grant awarded was originally titled "*Conducting time-sensitive research on barriers*
11 *to pregnancy care following policy shifts in the Midwest: The Pathways Study*." A panel of expert
12 reviewers scored the proposal in the top 5 percent of all submitted grants during that application review
13 cycle, and provided feedback that the research was likely to have a "high impact on the field of
14 reproductive health science and likely to inform geography-specific interventions to address urgent
15 access challenges in the Midwest." Additionally, reviewers noted "the critical nature of the data being
16 collected to identify the impact of bans on millions of Americans" and "the outstanding
17 multidisciplinary team, excellent pilot data to support feasibility of approach, and rigorous mixed
18 methods approach to answering the research objectives."

19 18. As originally awarded, the project involved a mixed-methods study to examine the
20 barriers to abortion care faced by pregnant Midwesterners following the June 2022 Supreme Court
21 opinion in *Dobbs v. Jackson Women's Health* and the passage of abortion bans in multiple Midwestern
22 states, and the longitudinal impact of those barriers on pregnancy and other physical, mental, and
23 financial health outcomes. To understand the barriers faced by pregnant people seeking abortion in the
24 Midwest amidst these rapidly changing political shocks and to quantify the impact of these restrictions
25 on their health and lives, unbiased, locally relevant data were urgently needed. Yet, most abortion access
26 research had recruited participants from clinics—participants who, by virtue of having gotten to an
27 abortion clinic, represent a population that was able to overcome many barriers to care, and further,
28 excludes people who use telemedicine or self-manage their abortions, and those who continue their

1 pregnancies. A clinic-based sampling mechanism thus induces selection bias, resulting in research that
2 misses or underestimates barriers to care. To address these methodological limitations, our research
3 sought to (1) expand recruitment to the full population of people seeking abortion, not just those who
4 make it to a clinic, (2) sensitively measure barriers and facilitators to abortion care, (3) capture the full
5 set of possible pregnancy pathways (including miscarriage, birth, clinical abortion, telemedicine
6 abortion, self-managed abortion) and their sequelae over time, and (4) ensure data were sufficiently
7 powered to answer nuanced questions at the regional level. To address this time-sensitive need in an
8 underserved region, we proposed four linked aims in a two-phase study. In the first six months of the
9 R61, we would recruit 500 pregnant people searching for information about abortion online to identify
10 via surveys and characterize via in-depth interviews the barriers people face while seeking abortion in
11 all 12 Midwest states. In the second (R33) phase of the study, we would follow these participants
12 forward in time with additional surveys at 4 and 10 months to measure who succeeded in obtaining
13 abortion and who did not, and the implications of their pregnancy outcome on broader physical, mental,
14 and socioeconomic health outcomes across restrictive versus permissive states. Finally, we would
15 implement a human-centered design approach to engage abortion fund leaders and Midwesterners who
16 had sought abortions to develop and test messages to address knowledge barriers or belief gaps
17 identified in the R61 phase that limit access to abortion. Findings from this study would drive more
18 informed, geography-specific interventions to address urgent access challenges in the Midwest.

19 19. On May 30, 2025, at the requested date of two months before the end of our R61 award
20 year, we submitted a progress report to the NICHD to document the activities during the award year and
21 progress toward our R61 goals and milestones. This progress report was a necessary step to transition
22 the grant from the R61 phase to the R33 phase. In the report, we detailed grant activities and noted that
23 we had met or exceeded all R61 phase milestones. To transition from the R61 to R33 phase, the NIH
24 staff must determine that the awardees achieved the R61 goals and milestones, review and approve the
25 transition application package, and confirm availability of funds. My understanding is that the approval
26 process for transitioning the grant from an R61 to an R33 historically does not involve renegotiation of
27 the aims or language describing the research.

20. In that first year of the grant, we met and exceeded all the goals and milestones we set out for the R61 year. Specifically, our goals were: (1) to collect baseline survey data from 500 pregnant Midwesterners about experiences seeking abortion care (at the time of the progress report, we had data from 582 pregnant Midwesterners); (2) to conduct 30 in-depth interviews with abortion-seekers to characterize barriers to pregnancy-related care (at the time of the progress report, we had 38 in-depth interviews complete); (3) to have professionally transcribed all interview audio recordings and have developed a codebook for analysis of the interviews (both completed); and (4) to have conducted preliminary quantitative analysis of barriers to pregnancy-related care in the Midwest. Each of these goals was achieved and clearly detailed in the progress report.

21. Presenting at conferences and publishing articles are both core activities for scientists and necessary for the fulfillment of the aims of a research grant. Both are standard ways that researchers share their work with subject matter experts and obtain peer review and feedback, allowing for an iterative process to refine analyses and findings, address gaps, and ensure scientific rigor. Given the focus of the award on rapid research in the wake of time-sensitive changes, we focused particularly intensely throughout the award in identifying opportunities to share findings, even if preliminary, with relevant audiences.

22. In October 2024, myself and one other member of the research team presented preliminary learnings from the study regarding online survey recruitment to a large, national conference. Topics included sharing best practices for implementing our online recruitment methodology in a shifting and uncertain policy environment, with implications for other researchers studying policy shifts. Additionally, the research team submitted four research abstracts and one workshop session to the Society of Family Planning Annual Meeting to share key findings from the surveys and interviews collected in the R61 phase. We were selected for the workshop, and were able to host an entire 75-minute session on preliminary findings from the study to an audience of several hundred family planning researchers, clinicians, and advocates. We continue to work with our advisory board partners to identify the most impactful ways of safely sharing study data with pregnant Midwesterners as well, as they navigate their options for care. Four peer-reviewed publications from the full study dataset are now underway.

23. Instead of the process that—to my understanding—would historically have occurred to transition us from the R61 to R33 phase focusing only on the progress we made towards the aims of our grant and availability of funds, we were requested to make “clarifications” to the public facing language in our aims and abstract. On August 28, 2025, almost two months after funding had lapsed on the R61, NIH notified us that it had finished reviewing our transition application and was requesting clarifications to the public facing language “to eliminate any confusion about our project’s alignment with priorities.” The suggested clarifications included removing the word “abortion”, changing “policy restrictions” to “policy changes”, as well as changing “pregnant people” to “pregnant women”, among other suggestions. We were told we could accept or reject the suggested edits, but that our final revisions were needed by the next day, and my understanding was that if we did not comply with the requested changes the grant would not be funded. At the time these changes were requested, the NIH had already terminated an R01 on which I was PI – hence, the threat of termination did not feel abstract, but very real and present.

24. Changing the language in our grant in the manner required by NIH was not an easy decision. It felt clear that this was an attempt to censor the word “abortion” from active NIH grants, to diminish the harm of abortion-related restrictions, and to minimize or erase the existence of pregnant people who identify as transgender men or other gender diverse identities other than “pregnant women”. The requests had nothing to do with the scientific methods, activities, or rigor of the research – they only served to make the study aims and focus less clear. However, given the delay in approval of our R33 transition application, and that we were already almost two months into unfunded territory with nowhere to charge staff salaries for their time on this study, we felt pressured to accept the changes, or risk not being awarded the R33. After much discussion as a team, we decided a greater harm would be to lose the funding and not be able to complete the research we and hundreds of study subjects had already put so much into—so we accepted the suggested edits and submitted it back to the NIH the following day, as requested, in the hopes it would protect our grant from being terminated. This decision process required multiple conversations, much confusion, uncertainty, and anxiety, and ultimately many hours of staff time that could have instead been devoted to the research.

1 25. Nevertheless, on September 2, 2025 (about 4 business days after submitting the revised
2 public facing documents), the transition to the R33 phase of the project was finally approved with the
3 first year of the R33 running until May 31, 2026.

4 26. Attached hereto as **Exhibit 2** is a true and correct copy of the R33 grant's NOA.

5 27. Since the budget period for the second year of the grant was truncated and set to run from
6 September 10, 2025 to May 31, 2026, on April 15, 2026, Indiana University submitted our required
7 Research Performance Progress Report ("RPPR") necessary for non-competitive renewal. The RPPR is
8 a standardized progress report that NIH grantees must submit every year, six weeks prior to the end of
9 the grant period, to document project accomplishments (milestones, publications, presentations, etc.),
10 challenges, compliance, and financial status, as well as plans for the year ahead. Additionally, RPPRs
11 include a section to report on the project participants—both the study team, as well as research subjects.
12 My understanding, informed by my prior experience as well as conversations and guidance from
13 colleagues, is that the RPPR is used to help the investigator(s) communicate to the program officer and
14 larger NIH staff how the research project is progressing against stated goals. For a grant governed by the
15 Standard Noncompeting Award Process ("SNAP") as mine is, my understanding is that the annual
16 review is never grounds for termination or non-renewal, except for the extremely rare event when an
17 investigator fails to comply with the terms of the award, is guilty of scientific misconduct, or when a
18 project is no longer viable. None of those conditions were true for our grant. All to say, we did not
19 expect to be asked to censor the language in our peer-reviewed, highly scored, and funded grant for
20 which we had met and exceeded all milestones.

21 28. Instead of receiving the NOA for the third year of the grant in a timely fashion (the
22 second year of the R33 phase), the budget end date passed without word from NIH on renewal. For
23 weeks, we received no NOA and no explanation for the delay.

24 29. However, upon inquiring in July 2026 about the approximately 2 month delay in our
25 grant, we received an email from the program officer stating that the award "appears to have been
26 stopped after release by the Office of Extramural Research, but we have not yet received information as
27 to why."

28 30. Attached hereto as **Exhibit 3** is a true and correct copy of the email we received.

1 31. Two weeks later, the program officer emailed us to say that the Office of Extramural
2 Research provided feedback stating “This grant's public-facing documents were clearly written to
3 obscure what it is about. Please work with the grantee to clarify what the researchers are studying and
4 what interventions could be informed by the work that could be conducted by the healthcare system, as
5 opposed to through legislative changes. If the only possible impactful intervention would be legislation,
6 it is not in the mission of the NIH.” (emphasis in original).

7 32. Attached hereto as **Exhibit 4** is a true and correct copy of the follow up email we
8 received.

9 33. I was confused that NIH would object to language in my grant as being too vague after
10 having pressured me to adopt the vaguer language months prior. I immediately felt nervous that we were
11 caught in some form of procedural trap, but that if we failed to comply, the NIH might terminate our
12 grant. Again, this fear of termination was very real for me, as the NIH had terminated another of my
13 grants just last year.

14 34. I was also perplexed and confused about the language in the email regarding legislative
15 changes. The call for proposals to which I applied specifically requested research documenting the
16 impact of policy or legislative changes, so I did not understand how or why I was meant to describe our
17 research project without using the words from the funding mechanism. I spoke with my program officer,
18 who informed me that NIH was raising new objections to research that was thought to relate to public
19 policy. She expressed concern that if I did not revise my grant description and aims to remove references
20 to public policy, the grant would likely be terminated.

21 35. While researchers cannot control the uses of their research findings once published, and
22 thus any research may ultimately have legislative impact, my work is fundamentally about public health
23 and public health interventions. In addition, I am aware that NIH funds many R01s in a host of areas that
24 impact policies at all levels of governance, from hospital policies to national and international
25 guidelines, so my sense is that NIH is selectively applying this new objection to grants thought to
26 influence public policy to research that it otherwise disfavors. Indeed, the very program announcement
27 (PA-22-233) that funded my award specifically identified policymakers as a target audience – stating
28

1 that the findings from the research should maximize “learning opportunities to better inform health care
2 and public health efforts, as well as policymakers.”

3 36. Yet again, it was a difficult decision to decide if and how to comply with the requests
4 from the NIH/OER regarding the public facing language of our grant. The requests were not based on
5 scientific value, integrity, or clarity. Instead, the NIH requests felt designed to obfuscate the intention
6 and aims of our research study—particularly to diminish the centrality of abortion policy and its impact
7 on public health—to serve agency censorship policies while adding no value or rigor to the research
8 itself. The NIH had not identified any limitations or critiques of our scientific methods, and is instead
9 censoring how we described the goals and focus. Myself, my colleagues at Ibis and Indiana University,
10 and others exhausted much staff time on deliberating these changes, making them, and proceeding in an
11 iterative process until the changes were deemed acceptable. This was distressing, confusing, and
12 overshadowed throughout by a fear of termination if we failed to comply—and at the same time,
13 concern that by complying we may also somehow be making our grant more vulnerable, all for a grant
14 that is noncompeting and should not have been renegotiated at all.

15 37. After weeks of uncertainty and fear that the grant would be terminated, on September 2,
16 2026, NIH issued the NOA for the third year of our award.

17 38. Attached hereto as **Exhibit 5** is a true and correct copy of the R33 grant’s NOA for the
18 third year.

19 39. While the award was issued, I continue to fear that the grant will be terminated. Since
20 NIH has now forced us to go through multiple rounds of revision on this grant, each time threatening to
21 terminate the grant if we do not comply, I am worried that NIH will initiate yet another forced revision
22 process or even suddenly summarily terminate the grant as they did in 2025 with another Ibis grant on
23 which I am PI and as I know has happened to many other researchers. The constant threat of termination
24 has enormous repercussions for the research. My research team and I feel constant stress and anxiety
25 about whether the funds for our salaries will be suddenly and capriciously terminated, and uncertain how
26 to advise my existing research team members, for fear that there will be a termination and I will have to
27 suddenly let them go. We feel unable to plan for future team meetings and conference presentations due
28

1 to the uncertainty imposed by the threat of termination, and we are worried that speaking up about this
2 experience will threaten our ability to conduct research in the future.

3 40. In addition, the third year NOA included a term that states, "SPECIAL TERM AND
4 CONDITION: The recipient has revised the Abstract, Public Health Relevance Statement, and Specific
5 Aims to ensure alignment with current agency priorities in [Training future biomedical scientists and/or
6 Promoting research focused on scientifically valid, measurable health outcomes]. The project must be
7 carried out in accordance with the revised plan/section submitted on DATE, which reflects the agreed
8 upon updates. In accordance with this renegotiation, NIH funds may only be used to support activities
9 within the revised scope of the award as described in the documents dated 08/10/2026. NIH funds may
10 not be used to support activities that are not consistent with the revised scope of the award."

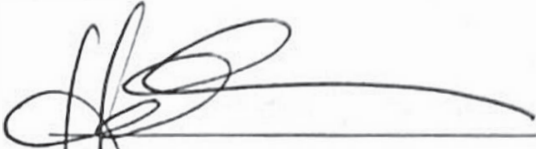
11 41. I am fearful that NIH will terminate my funding if I speak or write about my work or
12 present my findings in ways that differ from the language that NIH required us to adopt.

13 42. NIH funding is critical to my ability to conduct research at Ibis. But in light of NIH's
14 current censorship policies requiring me to obfuscate my research, and given my recent prior
15 experiences with grant termination and the constant ongoing threat of termination over the last year and
16 a half, I have for now halted putting together new applications to NIH that I would otherwise have
17 pursued. Preparing an NIH application is a laborious process, and NIH's actions have led me to believe
18 that the applications to NIH would likely be denied irrespective of scientific merit or would require me
19 to describe my research in ways that are vague and inaccurate in order to pass through NIH's screens for
20 disfavored research. That has an enormous impact on my ability to move forward with critical research
21 or to build on the findings of this research in the most impactful way, which ultimately has a detrimental
22 impact on public health.

23 43. I understand that, as a class representative, I represent the interests of everyone in the
24 class, and not just myself. I am prepared to stay informed about what is happening with my case and
25 stay in touch with my attorneys to give them information they need. I am committed to being a class
26 representative because I do not want other researchers to be subjected to the same unlawful policies and
27 actions that I have experienced. I have never served as a class representative in any prior action.
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1 44. I declare under penalty of perjury that the foregoing is true and correct, and that this
2 declaration was executed at ~~San Francisco~~ California this 16 day of September 2026.

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Heidi Moseson

Exhibit 1



Recipient Information	Federal Award Information																								
1. Recipient Name TRUSTEES OF INDIANA UNIVERSITY 980 INDIANA AVE RM 2232 INDIANAPOLIS, IN 46202	11. Award Number 1R61HD116143-01																								
2. Congressional District of Recipient 07	12. Unique Federal Award Identification Number (FAIN) R61HD116143																								
3. Payment System Identifier (ID) 1356001673A1	13. Statutory Authority 42 USC 241 42 CFR PART 52																								
4. Employer Identification Number (EIN) 356001673	14. Federal Award Project Title Time sensitive research on barriers to pregnancy care																								
5. Data Universal Numbering System (DUNS) 603007902	15. Assistance Listing Number 93.865																								
6. Recipient's Unique Entity Identifier SHHBRBAPSM35	16. Assistance Listing Program Title Child Health and Human Development Extramural Research																								
7. Project Director or Principal Investigator Tracey Wilkinson, MD (Contact) tracwilk@iu.edu 317-278-0552	17. Award Action Type New Competing																								
8. Authorized Official Mr. Steven Allen Martin	18. Is the Award R&D? Yes																								
Federal Agency Information	<table border="1"><thead><tr><th colspan="2">Summary Federal Award Financial Information</th></tr></thead><tbody><tr><td colspan="2">19. Budget Period Start Date 08/20/2024 – End Date 07/31/2025</td></tr><tr><td>20. Total Amount of Federal Funds Obligated by this Action</td><td>\$436,905</td></tr><tr><td>20 a. Direct Cost Amount</td><td>\$360,681</td></tr><tr><td>20 b. Indirect Cost Amount</td><td>\$76,224</td></tr><tr><td>21. Authorized Carryover</td><td></td></tr><tr><td>22. Offset</td><td></td></tr><tr><td>23. Total Amount of Federal Funds Obligated this budget period</td><td>\$436,905</td></tr><tr><td>24. Total Approved Cost Sharing or Matching, where applicable</td><td>\$0</td></tr><tr><td>25. Total Federal and Non-Federal Approved this Budget Period</td><td>\$436,905</td></tr><tr><td colspan="2">26. Project Period Start Date 08/20/2024 – End Date 07/31/2025</td></tr><tr><td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td><td>\$436,905</td></tr></tbody></table>	Summary Federal Award Financial Information		19. Budget Period Start Date 08/20/2024 – End Date 07/31/2025		20. Total Amount of Federal Funds Obligated by this Action	\$436,905	20 a. Direct Cost Amount	\$360,681	20 b. Indirect Cost Amount	\$76,224	21. Authorized Carryover		22. Offset		23. Total Amount of Federal Funds Obligated this budget period	\$436,905	24. Total Approved Cost Sharing or Matching, where applicable	\$0	25. Total Federal and Non-Federal Approved this Budget Period	\$436,905	26. Project Period Start Date 08/20/2024 – End Date 07/31/2025		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$436,905
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9. Awarding Agency Contact Information Mahasin Ingram EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ingrammk@mail.nih.gov (201) 780-0309	28. Authorized Treatment of Program Income Additional Costs																								
10. Program Official Contact Information Ronna Popkin EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ronna.popkin@nih.gov 301-827-5121	29. Grants Management Officer - Signature Mahasin Ingram																								
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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 – 1R61HD116143-01

Principal Investigator(s):

Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward+iu@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$436,905 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University 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 R61HD116143. 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,

Mahasin Ingram
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	\$58,274
Fringe Benefits	\$12,839
Personnel Costs (Subtotal)	\$71,113
Travel	\$3,225
Other	\$30,960
Subawards/Consortium/Contractual Costs	\$255,383
 Federal Direct Costs	 \$360,681
Federal F&A Costs	\$76,224
Approved Budget	\$436,905
Total Amount of Federal Funds Authorized (Federal Share)	\$436,905
TOTAL FEDERAL AWARD AMOUNT	\$436,905
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$436,905

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$436,905	\$436,905

Fiscal Information:

Payment System Identifier: 1356001673A1
Document Number: RHD116143A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	\$436,905

NIH Administrative Data:

PCC: PDB -RP / **OC:** 41021 / **Released:** 08/15/2024
Award Processed: 08/19/2024 12:16:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R61HD116143-01

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 – 1R61HD116143-01

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

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

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

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

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

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

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

This 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) R61HD116143. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

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

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

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

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

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

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

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

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

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R61HD116143-01

Clinical Trial Indicator: No

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

RESTRICTION: This award is being made without a currently valid certification of Institutional Review Board (IRB) approval consistent with 45 CFR Part 46 and is issued with the following restriction [for these studies]: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of IRB approval certification. No funds may be drawn down from the Payment Management System and no obligations may be made against Federal funds for any research involving human subjects prior to issuance of a revised Notice of Award rescinding this restriction.

IRB approval verification must be submitted within **60 days** of the date of this Notice of Award to the Grants Management Specialist (GMS). Please contact the GMS if the IRB approval will be delayed beyond 60 days. Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

REDUCTION: In order to meet NICHD program objectives within FY2024 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

DELAYED START DATE: This award includes funds for twelve months of support but is awarded for less than twelve months.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/31/2023.

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

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

SUBPROJECT: Subproject funding information is available via the [NIH RePORTER](#) System.

TRANSITION: 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 **R33** 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.

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

Budget	Year 1
DMS Costs	\$0

SPREADSHEET SUMMARY

AWARD NUMBER: 1R61HD116143-01

INSTITUTION: Trustees of Indiana University

Budget	Year 1
Salaries and Wages	\$58,274
Fringe Benefits	\$12,839
Personnel Costs (Subtotal)	\$71,113
Travel	\$3,225
Other	\$30,960
Subawards/Consortium/Contractual Costs	\$255,383
TOTAL FEDERAL DC	\$360,681
TOTAL FEDERAL F&A	\$76,224
TOTAL COST	\$436,905

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	58.5%
F&A Cost Base 1	\$130,298
F&A Costs 1	\$76,224

Exhibit 2



Recipient Information	Federal Award Information																								
1. Recipient Name TRUSTEES OF INDIANA UNIVERSITY 980 INDIANA AVE RM 2232 INDIANAPOLIS, IN 46202	11. Award Number 4R33HD116143-02																								
2. Congressional District of Recipient 07	12. Unique Federal Award Identification Number (FAIN) R33HD116143																								
3. Payment System Identifier (ID) 1356001673A1	13. Statutory Authority 42 USC 241 42 CFR 52																								
4. Employer Identification Number (EIN) 356001673	14. Federal Award Project Title Time sensitive research on barriers to pregnancy care																								
5. Data Universal Numbering System (DUNS) 603007902	15. Assistance Listing Number 93.865																								
6. Recipient's Unique Entity Identifier SHHBRBAPSM35	16. Assistance Listing Program Title Child Health and Human Development Extramural Research																								
7. Project Director or Principal Investigator Tracey Wilkinson, MD (Contact) tracwilk@iu.edu 317-278-0552	17. Award Action Type Extension with or without funds																								
8. Authorized Official Mr. Steven Allen Martin	18. Is the Award R&D? Yes																								
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10. Program Official Contact Information Ronna Popkin EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ronna.popkin@nih.gov 301-827-5121	29. Grants Management Officer - Signature Mahasin Ingram																								
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EXPLORATORY DEVELOPMENT AWARD
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 – 4R33HD116143-02

Principal Investigator(s):

Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward+iu@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$481,641 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R33HD116143. 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,

Mahasin Ingram
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	\$65,337
Fringe Benefits	\$15,379
Personnel Costs (Subtotal)	\$80,716
Travel	\$23,865
Other	\$62,734
Subawards/Consortium/Contractual Costs	\$214,399
 Federal Direct Costs	 \$381,714
Federal F&A Costs	\$99,927
Approved Budget	\$481,641
Total Amount of Federal Funds Authorized (Federal Share)	\$481,641
TOTAL FEDERAL AWARD AMOUNT	\$481,641
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$481,641

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
2	\$481,641	\$481,641
3	\$427,161	\$427,161
4	\$498,724	\$498,724
5	\$448,362	\$448,362

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

Fiscal Information:

Payment System Identifier: 1356001673A1
Document Number: RHD116143B
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025	2026	2027	2028
HD	8014702	\$481,641	\$427,161	\$498,724	\$448,362

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

NIH Administrative Data:

PCC: PDB -RP / **OC:** 41025 / **Released:** 09/09/2025
Award Processed: 09/15/2025 05:21:06 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 4R33HD116143-02

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 – 4R33HD116143-02

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

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

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

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R33HD116143. 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 (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 4R33HD116143-02

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.

ESCALATION: In accordance with FY2025 NICHD fiscal policy, escalation on recurring costs has been removed.

RECYCLING: This award includes funds for twelve months of support but is awarded for less than twelve months. Noncompeting Continuation awards will cycle on **06/01**. NICHD is taking this action to redistribute start dates more evenly throughout the fiscal year.

FUNDING: In order to meet NICHD program objectives within FY2025 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/31/2023.

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

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

SUBPROJECT: Subproject funding information is available via the [NIH RePORTER](#) System.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 10/31/2023, and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice [NOT-OD-06-054](#).

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: 4R33HD116143-02

INSTITUTION: Trustees of Indiana University

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$65,337	\$65,337	\$65,337	\$65,337
Fringe Benefits	\$15,379	\$15,379	\$15,379	\$15,379
Personnel Costs (Subtotal)	\$80,716	\$80,716	\$80,716	\$80,716
Travel	\$23,865	\$3,225	\$3,225	\$3,225
Other	\$62,734	\$62,734	\$105,734	\$73,960
Subawards/Consortium/Contractual Costs	\$214,399	\$194,681	\$194,681	\$194,681
Publication Costs			\$2,150	\$2,150
TOTAL FEDERAL DC	\$381,714	\$341,356	\$386,506	\$354,732
TOTAL FEDERAL F&A	\$99,927	\$85,805	\$112,218	\$93,630
TOTAL COST	\$481,641	\$427,161	\$498,724	\$448,362

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	58.5%	58.5%	58.5%	58.5%
F&A Cost Base 1	\$170,815	\$146,675	\$191,825	\$160,051
F&A Costs 1	\$99,927	\$85,805	\$112,218	\$93,630

Exhibit 3

Outlook

Fw: Checking-In

From Heidi Moseson <hmoseson@ibisreproductivehealth.org>

Date Fri 9/18/2026 4:41 PM

To Olga Akselrod <oakselrod@aclu.org>

This Message Is From an External Sender

This message came from outside your organization.

From: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>

Sent: Wednesday, July 15, 2026 2:58 PM

To: tracwilk@iu.edu <tracwilk@iu.edu>

Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>

Subject: RE: Checking-In

Hi Tracey and Heidi,

We are looking into this. It appears to have been stopped after release by the Office of Extramural Research, but we have not yet received information as to why.

Thanks for your patience,

Ronna

Ronna Popkin, PhD

Program Officer, Population Dynamics Branch

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

6710B Rockledge/Rm 2209B

Office Phone: 301-827-5121

Mobile Phone: 301-646-8379

ronna.popkin@nih.gov

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>

Sent: Wednesday, July 15, 2026 1:47 PM

To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>

Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>

Subject: [EXTERNAL] Re: Checking-In

Dear Ronna-

Hello from Indiana—where it is HOT today! I am currently digging out of my InBox after being OOO for a bit and wanted to quickly reach out and see if you had any updates with regard to our R33 grant. I logged into eRA recently and saw that there was a “pending” listed under Application Status from 6/23 and so was hoping you may have an update on your end! Looking forward to hearing from you!

Sincerely
Tracey

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine

Associate Professor of Pediatrics and Obstetrics & Gynecology

317-278-0552 | tracwilk@iu.edu | [Schedule a virtual meeting](#)

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>

Date: Thursday, June 25, 2026 at 3:00 PM

To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>

Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>

Subject: Re: Checking-In

Dear Ronna-

Hello! I hope you are having a wonderful summer so far! I wanted to quickly reach out to you regarding our RPPR and see if you had any updates from your end! I know my previous email landed when you were out-of-office, so I wanted to quickly send another with the hope you may have recovered from a deep, deep InBox 😊

Sincerely
Tracey

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine

Associate Professor of Pediatrics and Obstetrics & Gynecology

317-278-0552 | tracwilk@iu.edu | [Schedule a virtual meeting](#)

From: Wilkinson, Tracey Allyson <tracwilk@iu.edu>

Date: Wednesday, June 3, 2026 at 12:58 PM

To: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>

Cc: Heidi Moseson <hmoseson@ibisreproductivehealth.org>

Subject: Checking-In

Dear Ronna-

Hello! I hope this email finds you doing well! We wanted to quickly email you to see if you had any updates on our recent RPPR that was submitted for R33HD116143-03. We realize that this is an incredibly busy time of year, but would love any updates you may have as the fiscal year started on 6/1/26. Thanks and hope to see you at SFP this fall in-person if not sooner!

Sincerely
Tracey & Heidi

Tracey A. Wilkinson, MD, MPH | Indiana University School of Medicine

Associate Professor of Pediatrics and Obstetrics & Gynecology

317-278-0552 | tracwilk@iu.edu | [Schedule a virtual meeting](#)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Exhibit 4



Fw: Clarifications to the Abstract, Aims, and Narrative for 5R33HD116143-03 (PI: Wilkinson)

From Heidi Moseson <hmoseson@ibisreproductivehealth.org>

Date Fri 9/18/2026 4:41 PM

To Olga Akselrod <oakselrod@aclu.org>

This Message Is From an External Sender

This message came from outside your organization.

From: Popkin, Ronna (NIH/NICHD) [E] <ronna.popkin@nih.gov>

Sent: Friday, July 31, 2026 3:06 PM

To: tracwilk@iu.edu <tracwilk@iu.edu>; Heidi Moseson <hmoseson@ibisreproductivehealth.org>

Cc: jambecke@iu.edu <jambecke@iu.edu>; NICHD HD eRA Notifications (NIH/NICHD) <hderanotifications@mail.nih.gov>; McCall, Mahasin (NIH/NICHD) [E] <mahasin.ingram@nih.gov>

Subject: Clarifications to the Abstract, Aims, and Narrative for 5R33HD116143-03 (PI: Wilkinson)

Dear Tracey and Heidi,

The NIH Office of Extramural Research returned this project to us with the following feedback:

“This grant's public-facing documents were clearly written to obscure what it is about. Please work with the grantee to clarify what the researchers are studying and what interventions could be informed by the work that could be conducted by the healthcare system, as opposed to through legislative changes. If the only possible impactful intervention would be legislation, it is not in the mission of the NIH.”

My suggestion is to revise your Aims, Abstract, and Public Health Relevance/Project Narrative to more clearly convey that the project is investigating how changes in access to abortion care have impacted the health of pregnant women, to include a hard-to-reach and relatively understudied population of pregnant women (women seeking medication abortion outside of the clinic), and that the goal in Aim 3 is quite clearly NOT to change laws/policies but rather to optimize care for women across the Midwest regardless of their policy environment. Also, I have approved some changes to the approach given the issues you all faced in data collection. Please revise the documents to reflect those changes—you do not need to refer to the original design. Describe what you actually did in the R61 and what you are doing now in the R33, and be sure to underscore how the findings from this project will be able to inform and impact future *clinical care and interventions*. Thanks!

Please have your signing official email to Mahasin revised versions of your summary documents (NO tracked changes or references, please!) using the attached Word document template, cc'ing you and me. Please be sure it is emailed as a Word attachment and not a PDF.

Once the revisions are emailed to Mahasin, I will review and either approve or recommend additional clarifications. Thanks for your patience as we awaited feedback from OER on your project and thanks in advance for addressing these comments promptly. I will be out of the office Monday 8/3 – Wednesday 8/5, but if you complete the changes before then, please have your SO email them so I can review as soon as I'm back.

Thanks!

Ronna

Ronna Popkin, PhD

Program Officer, Population Dynamics Branch

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

6710B Rockledge/Rm 2209B

Office Phone: 301-827-5121

Mobile Phone: 301-646-8379

ronna.popkin@nih.gov

Exhibit 5



Recipient Information	Federal Award Information																								
1. Recipient Name TRUSTEES OF INDIANA UNIVERSITY 980 INDIANA AVE RM 2232 INDIANAPOLIS, IN 46202	11. Award Number 5R33HD116143-03																								
2. Congressional District of Recipient 07	12. Unique Federal Award Identification Number (FAIN) R33HD116143																								
3. Payment System Identifier (ID) 1356001673A1	13. Statutory Authority 42 USC 241 42 CFR 52																								
4. Employer Identification Number (EIN) 356001673	14. Federal Award Project Title Time sensitive research on barriers to pregnancy care																								
5. Data Universal Numbering System (DUNS) 603007902	15. Assistance Listing Number 93.865																								
6. Recipient's Unique Entity Identifier SHHBRBAPSM35	16. Assistance Listing Program Title Child Health and Human Development Extramural Research																								
7. Project Director or Principal Investigator Tracey Wilkinson, MD (Contact) Associate Professor tracwilk@iu.edu 317-278-0552	17. Award Action Type Non-Competing Continuation																								
8. Authorized Official James P Becker	18. Is the Award R&D? Yes																								
Federal Agency Information	<table border="1"><thead><tr><th colspan="2">Summary Federal Award Financial Information</th></tr></thead><tbody><tr><td colspan="2">19. Budget Period Start Date 06/01/2026 – End Date 05/31/2027</td></tr><tr><td>20. Total Amount of Federal Funds Obligated by this Action</td><td>\$427,161</td></tr><tr><td>20 a. Direct Cost Amount</td><td>\$341,356</td></tr><tr><td>20 b. Indirect Cost Amount</td><td>\$85,805</td></tr><tr><td>21. Authorized Carryover</td><td></td></tr><tr><td>22. Offset</td><td></td></tr><tr><td>23. Total Amount of Federal Funds Obligated this budget period</td><td>\$427,161</td></tr><tr><td>24. Total Approved Cost Sharing or Matching, where applicable</td><td>\$0</td></tr><tr><td>25. Total Federal and Non-Federal Approved this Budget Period</td><td>\$427,161</td></tr><tr><td colspan="2">26. Project Period Start Date 08/20/2024 – End Date 05/31/2029</td></tr><tr><td>27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period</td><td>\$908,802</td></tr></tbody></table>	Summary Federal Award Financial Information		19. Budget Period Start Date 06/01/2026 – End Date 05/31/2027		20. Total Amount of Federal Funds Obligated by this Action	\$427,161	20 a. Direct Cost Amount	\$341,356	20 b. Indirect Cost Amount	\$85,805	21. Authorized Carryover		22. Offset		23. Total Amount of Federal Funds Obligated this budget period	\$427,161	24. Total Approved Cost Sharing or Matching, where applicable	\$0	25. Total Federal and Non-Federal Approved this Budget Period	\$427,161	26. Project Period Start Date 08/20/2024 – End Date 05/31/2029		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$908,802
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27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$908,802																								
9. Awarding Agency Contact Information Mahasin Ingram EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ingrammk@mail.nih.gov (301) 480-7460	28. Authorized Treatment of Program Income Additional Costs																								
10. Program Official Contact Information Ronna Popkin EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT ronna.popkin@nih.gov 301-827-5121	29. Grants Management Officer - Signature Mahasin Ingram																								
30. Remarks Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.																									



EXPLORATORY DEVELOPMENT AWARD
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 – 5R33HD116143-03

Principal Investigator(s):

Heidi Serene Moseson Lidow, PHD
Tracey Wilkinson (contact), MD

Award e-mailed to: iuaward@iu.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$427,161 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Trustees of Indiana University in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R33HD116143. 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,

Mahasin Ingram
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	\$65,337
Fringe Benefits	\$15,379
Personnel Costs (Subtotal)	\$80,716
Travel	\$3,225
Other	\$62,734
Subawards/Consortium/Contractual Costs	\$194,681
 Federal Direct Costs	 \$341,356
Federal F&A Costs	\$85,805
Approved Budget	\$427,161
Total Amount of Federal Funds Authorized (Federal Share)	\$427,161
TOTAL FEDERAL AWARD AMOUNT	\$427,161
 AMOUNT OF THIS ACTION (FEDERAL SHARE)	 \$427,161

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	THIS AWARD	CUMULATIVE TOTALS
3	\$427,161	\$427,161
4	\$498,724	\$498,724
5	\$448,362	\$448,362

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

Fiscal Information:

Payment System Identifier: 1356001673A1
Document Number: RHD116143B
PMS Account Type: P (Subaccount)
Fiscal Year: 2026

IC	CAN	2026	2027	2028
HD	8014702	\$427,161	\$498,724	\$448,362

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

NIH Administrative Data:

PCC: PDB -RP / **OC:** 41025 / **Released:** 08/24/2026
Award Processed: 09/02/2026 12:18:54 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R33HD116143-03

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 – 5R33HD116143-03

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

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

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

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

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

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

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) R33HD116143. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

In accordance with the regulatory requirements provided at 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system that is found in [SAM.gov](https://sam.gov). Full reporting requirements and procedures are found in 2 CFR Part 200. This term does not apply to NIH fellowships.

Use of Supplies and Services for Harm Reduction Activities

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

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

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

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

Treatment of Program Income:

Additional Costs

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

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R33HD116143-03

Clinical Trial Indicator: No

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

SPECIAL TERM AND CONDITION: The recipient has revised the Abstract, Public Health Relevance Statement, and Specific Aims to ensure alignment with current agency priorities in [Training future biomedical scientists and/or Promoting research focused on scientifically valid, measurable health outcomes]. The project must be carried out in accordance with the revised plan/section submitted on DATE, which reflects the agreed upon updates. In accordance with this renegotiation, NIH funds may only be used

to support activities within the revised scope of the award as described in the documents dated 08/10/2026. NIH funds may not be used to support activities that are not consistent with the revised scope of the award.

DATA MANAGEMENT AND SHARING: Dissemination of study data will be in accordance with the recipient's accepted Data Management and Sharing Plan as stated in the application dated 10/31/2023.

HUMANS: 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".

CONSORTIUM: This award includes funds awarded for consortium activity with Ibis Reproductive Health, INC.

SUBPROJECT: Subproject funding information is available via the [NIH RePORTER](#) System.

MULTI-PI: The recipient must follow the Multiple Principal Investigator Leadership Plan included in the application dated 10/31/2023, and may not implement any changes in the plan without written NICHD prior approval.

Although the signatures of all PI/PD(s) are not required on prior approval requests, the recipient institution must secure and retain the signatures of all of PI/PD(s) within their own internal processes. See NIH Guide Notice [NOT-OD-06-054](#).

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: 5R33HD116143-03

INSTITUTION: Trustees of Indiana University

Budget	Year 3	Year 4	Year 5
Salaries and Wages	\$65,337	\$65,337	\$65,337
Fringe Benefits	\$15,379	\$15,379	\$15,379
Personnel Costs (Subtotal)	\$80,716	\$80,716	\$80,716
Travel	\$3,225	\$3,225	\$3,225
Other	\$62,734	\$105,734	\$73,960
Subawards/Consortium/Contractual Costs	\$194,681	\$194,681	\$194,681
Publication Costs		\$2,150	\$2,150
TOTAL FEDERAL DC	\$341,356	\$386,506	\$354,732
TOTAL FEDERAL F&A	\$85,805	\$112,218	\$93,630
TOTAL COST	\$427,161	\$498,724	\$448,362

Facilities and Administrative	Year 3	Year 4	Year 5
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Costs			
F&A Cost Rate 1	58.5%	58.5%	58.5%
F&A Cost Base 1	\$146,675	\$191,825	\$160,051
F&A Costs 1	\$85,805	\$112,218	\$93,630