EXHIBIT 24

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

DECLARATION OF KELLY BLANCHARD

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

1. I am the President of Ibis Reproductive Health (Ibis). I have served in that role since November 2004. Founded in 2002, Ibis is a global research organization whose mission is to drive change through bold, rigorous research and principled partnerships that advance sexual and reproductive autonomy, choice, and health worldwide.
2. I make this declaration on behalf of Ibis Reproductive Health in support of its Motion for Preliminary Injunction seeking to enjoin defendants from implementing or enforcing unlawful directives, and terminations of grants that supposedly no longer effectuate agency priorities, including research grant R01HD109320, which was terminated by the NIH in March 2025.
3. I have extensive training and experience in clinical and social science research and have led clinical trials and other qualitative and quantitative research for more than 20 years. I earned an MSc in Population and International Health from the Harvard School of Public Health and an AB from

Harvard College. I have published more than 140 articles in peer-reviewed scientific journals and serve as an expert peer reviewer for high-impact journals. Since 2004 as President of Ibis Reproductive Health I have provided strategic leadership of the organization and worked with our Senior Management Team to lead cutting edge research, build and maintain the critical principled partnerships to develop and implement that research, raise the funding needed to undertake this work, and disseminate and communicate research results to key stakeholders, including policy makers, clinicians, professional societies and norm setting bodies, and the general public to ensure our research and project work makes an impact.

Award of NIH Grant R01HD109320

1. Public health research is core to Ibis's work, which is informed by relationships and collaboration with communities, including transgender and gender diverse community members, to identify key gaps in information and resources concerning reproductive health, autonomy, and health care access for these populations. With offices in Cambridge, Massachusetts, Oakland, California, and Johannesburg, South Africa, Ibis has a highly trained and committed staff of demographers, epidemiologists, and public health researchers leading over 30 studies worldwide.
2. In September 2023, Ibis was awarded a National Institutes of Health ("NIH") Grant R01HD109320 titled "*Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality*" based on a panel of expert reviewers scoring the proposal in the top 2 percent of all submitted grants that cycle for its likelihood of exerting a sustained and positive impact on public health. A true and correct copy of this Notice of Award (NOA) is attached as **Exhibit A**. This five-year research grant anticipated providing approximately $2.2

million in funding[1] for a research project to evaluate innovative methods for improving the collection and quality of data in sexual and reproductive health (SRH) research for all people, including those who identify as transgender and gender diverse.

3. NIH Grant R01HD109320 was awarded to support the goal of enhancing research on the sexual and reproductive health of transgender, nonbinary, and intersex people (TNBI) people. The Institute of Medicine's report on "The Health of Lesbian, Bisexual, and Transgender People," called for NIH-supported research to address the methodological challenges that have impeded research on the health of transgender people – specifically, to improve strategies for reaching larger, more diverse samples of transgender persons in the United States. Historically, research on SRH has excluded or misclassified TNBI people due to presumptions that pregnancy and related outcomes can be experienced solely by cisgender women. However, TNBI people plan for and carry pregnancies, and thus require high-quality and evidence-based healthcare. Despite this need, existing data on the SRH needs of TNBI populations primarily come from convenience samples – small in size and/or limited in geographic scope. The dearth of representative data has meant, critically, that SRH providers do not have adequate evidence upon which to rely to ensure that the SRH needs of their TNBI patients are met within existing healthcare services – thereby contributing to lower quality care and SRH disparities among these populations.

4. With the Grant, Ibis intended to test methods of improving the representativeness of the research population, participant retention, and quality of collected data among TNBI people in the United States. Specifically, the research project sought to (1) recruit a large, diverse sample of TNBI people from across the United States, (2) collect longitudinal data on core SRH outcomes (virtually

[1] The Notice of Award provided the following recommended total awards for each year of the grant: YR 1 ($510,937); YR 2 ($482,443); YR 3 ($434,712); YR 4 ($424,119(; YR 5 ($405, 474).

no longitudinal data on these topics exist among TNBI people), and (3) improve retention and data quality among TNBI participants in SRH research as compared to standard methods.

5. Additionally, the research project sought to further a cross-cutting goal identified by the National Institute of Child Health and Human Development's (NICHD) 2020 and 2025 Strategic Plans – to address health disparities for sexual and gender minority people – and would have contributed evidence toward "Advancing Gynecologic, Andrologic, and Reproductive Health" and "Setting the Foundation for Healthy Pregnancies and Lifelong Wellness", two of the five core priorities of the NICHD 2025 Strategic Plan. The Grant went through a noncompetitive renewal process, and was renewed for the June 1, 2024 – May 31, 2025 budget cycle. A true and correct copy of this NOA, renewing the Grant is attached as **Exhibit B**. Per the standard noncompetitive renewal process, the Principal Investigator submitted a Research Performance Progress Report (RPPR) six weeks before the end of the first grant year, and after review by NICHD staff, the study was determined to be proceeding appropriately, and thus the second year of the Grant was awarded.
6. In addition to the primary research Grant, Ibis was awarded a supplemental grant for years 2 through 5 of the study, tied to the R01 Grant, which provided an additional $59,000 of funding per year. A true and correct copy of this supplemental award is attached as **Exhibit C**.
7. The preparation of this grant application took several years. The first conversation with a Program Officer at the NIH to begin development of this grant application took place in January 2019. The final revised R01 application was the result of over two years of conceptualization, relationship building, study design, drafting, and multiple expert consultations. The first draft of the application was submitted to the NICHD in October 2021. It was not funded and received reviewer feedback. The Principal Investigator then worked to revise the application based on those comments, with members of the research project team and partners in additional rounds of expert consultation and

review, alongside input from the NICHD Program Officer. These revisions took another six months before readiness for submission of the final revised application in July 2022, which was ultimately funded in September of 2023 - over four and a half years after preparation of the application first began.

8. Ibis's proposed research project was reviewed by a study section which scored the proposed project in the highest 2 percent of reviewed proposals. In the Summary Statement submitted by the panel of scientists, expert reviewers characterized the research as being "exceptionally high impact and has a high likelihood of profound and sustained impact on public health research and clinical practice" as well as having the potential to "significantly change the field by establishing new tools for assessing the relevance of key preventative health screenings in public health research and clinical practice," and that the study would "fill a massive gap in terms of research."
9. To the extent that the termination of this grant has prevented the collection of survey data, each week that goes by is another week where people are not being appropriately screened into clinical care and research that would be relevant for their bodies, leading to missed preventative care, or conversely, unnecessary preventive care. The screening tools the surveys would have tested were designed to identify improvements to clinical and research screening questions that could address these discordances. Further, each week that goes by without the contribution of this data to the field is a week where clinical providers do not have the evidence they need to provide evidence-based SRH care to TNBI people, including care related to fertility services, pregnancy, family formation, contraceptive use, and more. Leading professional and medical societies have emphasized the urgent need for these data, as have Americans who deserve to see themselves reflected in the research.

10. In the nearly two years since the Grant was awarded, Ibis has hired two full-time staff to serve as research coordinators and has invested thousands of staff hours in developing essential components of the research project – namely the various survey designs and methodologies to be tested for their ability to improve accuracy, completion, and quality of survey data. This work has included recruiting, convening, and seeking input from community advisory board members; conducting formative cognitive interviews; developing and programming a complex, highly novel and innovative online survey with randomization of key survey methodologies to be tested, formalizing research project partnerships with academic institutions and community partners; and seeking and securing institutional review board (IRB) approval of the research. The research team was poised to launch the first of several surveys and begin full data collection shortly after the termination letter was received.

Termination of NIH Grant R01HD109320

11. On March 20, 2025, in the midst of the second year of grant funding, I received a letter from the NIH notifying me that the funding for R01HD109320 was terminated. The termination letter stated that the R01HD109320 Grant "no longer effectuates agency priorities." The letter goes on to state that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. It is the policy of NIH not to prioritize these research programs . . . The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." A true and correct copy of this termination letter is attached as **Exhibit D**. The letter was signed by Michelle G. Bulls on behalf of Margaret Young, Chief Grants Management Officer for the NICHD.

12. I was not given any previous indication by NIH, the Institute, or the Program Officer that Ibis's R01HD109320 Grant was in jeopardy of being terminated.

13. The termination letter was vague and not scientifically accurate, nor does it explain how the agency decision was made or consider important aspects of the funded research. For example, the termination letter does not give a description of what is meant by "gender identity," nor was Ibis provided any clarification on why the grant was terminated based on the belief that "[r]esearch programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans." Existing research does not support this statement, and indeed, the panel of experts convened by the NIH concluded the opposite, that this research had a strong likelihood of exerting "profound and sustained impact on public health" for Americans.

14. On March 26, 2025, I received revised NOAs for both the primary grant [5R01HD109320-02] and the supplemental grant [3R01HD109320-02S1] indicating that the end of each grant was revised to March 21, 2025. True and correct copies of these revised NOAs are attached as **Exhibit E** and **Exhibit F**. These revised NOAs repeated the vague and inaccurate statement from the termination letter, and provided limited instructions for the close out of the Grant.

15. The implementation of this Grant to date has been in full compliance with the terms and conditions of the award, and the research is in full alignment with the stated priorities of the NIH broadly, and the NICHD specifically. Nor has Ibis provided consent for the termination.

16. The abrupt decision during an awarded grant year unjustly disrupts vital research with significant public health implications, and causes harm to Ibis's small, nonprofit research organization and its research project partners. As a result of the Grant termination in the midst of a grant year, Ibis is suddenly left without funding to support commitments to staff salary and benefits, and subaward

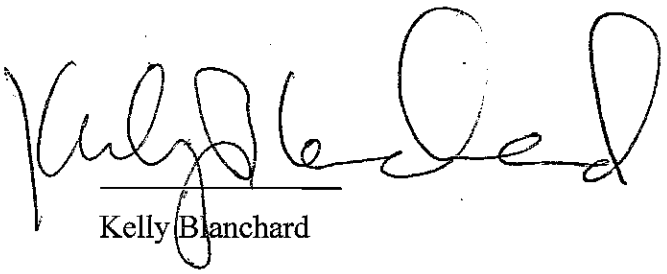
costs. Ibis cannot complete the urgently needed research that the NIH has already invested $1,047,555 over the past 22 months, leading to a potentially significant wasted investment. Additionally, the $1.4 million in research funding committed to Ibis in the NOA for the remaining 3-5 years of the grant was an important part of the $8 million annual operating budget for Ibis, as a small nonprofit organization.

17. As a result of the grant termination, Ibis must restructure research teams because of staffing pressures and seek additional funding to cover the salaries of four employees staffed on the project. This termination potentially puts at risk staff positions at Ibis if additional funds to cover staff time cannot be secured or other projects are not available to cover that time. Ibis has also had to pause the next phase of the research project, hindering collection of crucial data on SRH experiences and preferences from under-studied populations that independent expert NIH reviewers deemed urgently needed.

18. On April 16, 2025, I filed a letter of appeal to the NIH on behalf of Ibis, appealing the termination of R01HD109320. In the appeal, I challenged the grant termination on the basis that the termination letter received was generic, false, and not based on the merit of the science or progress of the research project in question. I am appealing the termination, but I do not know whether it is possible to or how to recharacterize my project in my appeal to fit within any new agency priorities because I do not understand the terms describing the reasons for termination or even what the new priorities are. I also do not know whether the appeal has any chance of success, given the language of the termination notice that the premise of my grant is incompatible with agency priorities.

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

Executed this 24th day of April, 2025.



Kelly Blanchard

EXHIBIT A

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

Notice of Award
FAIN# R01HD109320
Federal Award Date
02/09/2024

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
[redacted]

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFR8QTK9H5M5

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD
[redacted]

8. Authorized Official
Kelly Blanchard
[redacted]

Federal Agency Information

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

10. Program Official Contact Information
Ronna Popkin

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

Federal Award Information

11. Award Number
1R01HD109320-01A1

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

15. Assistance Listing Number
93.865

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

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09/21/2023 – **End Date** 05/31/2024	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$510,937
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$510,937
26. Project Period Start Date 09/21/2023 – **End Date** 05/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$510,937

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Yvonne C. Talley

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R01HD109320-01A1 REVISED

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to IBIS REPRODUCTIVE HEALTH 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 R01HD109320. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	$101,304
Fringe Benefits	$28,365
Personnel Costs (Subtotal)	$129,669
Consultant Services	$11,180
Other	$4,300
Subawards/Consortium/Contractual Costs	$306,480
Equipment or Facility Rental/User Fees	$20,747
Federal Direct Costs	$472,376
Federal F&A Costs	$38,561
Approved Budget	$510,937
Total Amount of Federal Funds Authorized (Federal Share)	$510,937
TOTAL FEDERAL AWARD AMOUNT	$510,937
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$510,937	$510,937
2	$482,443	$482,443
3	$434,712	$434,712
4	$424,119	$424,119
5	$405,474	$405,474

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

Fiscal Information:

Payment System Identifier: 1030382773A1
Document Number: RHD109320A
PMS Account Type: P (Subaccount)
Fiscal Year: 2023

IC	CAN	2023	2024	2025	2026	2027
HD	8014702	$51,714	$482,443	$434,712	$424,119	$405,474
OD	8025139	$459,223				

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**: 41021 / **Released**: Talley, Yvonne 02/08/2024
Award Processed: 02/09/2024 12:05:49 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HD109320-01A1 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01HD109320-01A1 REVISED

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

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

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

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

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Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD)
Office Of The Director, National Institutes Of Health (OD)

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 – 1R01HD109320-01A1 REVISED

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

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REVISION: This revised award reflects NICHD acceptance of the following documentation/information and removes the restriction indicated on the previous Notice of Award:

Previously pending items:

1. Updated Other Support

2. Institutional Review Board (IRB) approval

The previous terms and conditions of award remain in effect as stated below.

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

Funding Level
In order to meet NICHD program objectives within FY2023 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are reduced **24.9** percent determined by applying the same administrative reduction.

Escalation
In accordance with the NICHD FY2023 fiscal policy, escalation on recurring costs has been removed. See NICHD Funding Strategies for Fiscal Year 2023.

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Clinical Trial Terms

Dissemination Policy
The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **07/05/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

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

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of their knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in

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part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

Clinical Trial Study/Studies:
STUDY NUMBER: 427630

Risk Assessment
This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

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

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

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Consortium
This award includes funds awarded for consortium activity with the following:
Mount Holyoke College
Stanford University

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01HD109320-01A1 REVISED

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 1	Year 2	Year 3	Year 4	Year 5

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Salaries and Wages	$101,304	$111,382	$154,015	$154,015	$154,015
Fringe Benefits	$28,365	$31,187	$43,124	$43,124	$43,124
Personnel Costs (Subtotal)	$129,669	$142,569	$197,139	$197,139	$197,139
Consultant Services	$11,180	$4,318	$12,016	$12,016	$16,898
Travel			$1,878	$1,878	$3,755
Other	$4,300	$3,755	$3,755	$3,755	$3,755
Subawards/Consortium/Contractual Costs	$306,480	$268,902	$131,137	$120,544	$93,775
Equipment or Facility Rental/User Fees	$20,747	$22,811	$34,409	$34,409	$34,409
TOTAL FEDERAL DC	$472,376	$442,355	$380,334	$369,741	$349,731
TOTAL FEDERAL F&A	$38,561	$40,088	$54,378	$54,378	$55,743
TOTAL COST	$510,937	$482,443	$434,712	$424,119	$405,474

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	20.2%	20.2%	20.2%	20.2%	20.2%
F&A Cost Base 1	$190,896	$198,453	$269,197	$269,197	$275,956
F&A Costs 1	$38,561	$40,088	$54,378	$54,378	$55,743

Version: 13 - 8/3/2022 12:59 PM | Generated on: 2/9/2024 12:05 AM

EXHIBIT B

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

Notice of Award
FAIN# R01HD109320
Federal Award Date
08/20/2024

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
[redacted]

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFR8QTK9H5M5

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD
[redacted]

8. Authorized Official
Kelly Blanchard
[redacted]

Federal Agency Information

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

10. Program Official Contact Information
Ronna Popkin

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

Federal Award Information

11. Award Number
5R01HD109320-02

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

15. Assistance Listing Number
93.865

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

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 05/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$477,618
20 a. Direct Cost Amount	$437,931
20 b. Indirect Cost Amount	$39,687
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$477,618
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$477,618
26. Project Period Start Date 09/21/2023 **– End Date** 05/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$988,555

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Yvonne C. Talley

30. Remarks

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

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R01HD109320-02

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $477,618 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to IBIS REPRODUCTIVE HEALTH 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 R01HD109320. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/20/2024 12:18 AM

Salaries and Wages	$110,268
Fringe Benefits	$30,875
Personnel Costs (Subtotal)	$141,143
Consultant Services	$4,275
Other	$3,717
Subawards/Consortium/Contractual Costs	$266,213
Equipment or Facility Rental/User Fees	$22,583
Federal Direct Costs	$437,931
Federal F&A Costs	$39,687
Approved Budget	$477,618
Total Amount of Federal Funds Authorized (Federal Share)	$477,618
TOTAL FEDERAL AWARD AMOUNT	$477,618
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$477,618

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$477,618	$477,618
3	$434,712	$434,712
4	$424,119	$424,119
5	$405,474	$405,474

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

Fiscal Information:
Payment System Identifier: 1030382773A1
Document Number: RHD109320A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027
HD	8014702	$427,618	$434,712	$424,119	$405,474
OD	8055729	$50,000	$0	$0	$0

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**: 08/17/2024
Award Processed: 08/20/2024 12:18:52 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD109320-02

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 – 5R01HD109320-02

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

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references cited above.)

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) Office Of The Director, National Institutes Of Health (OD)

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

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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 – 5R01HD109320-02

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.

Funding Level
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Co-fund
Co-funding support in the amount of $50,000 from the Office of Behavioral and Social Sciences Research (OBSSR).

Clinical Trial Terms

Dissemination Policy
The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **07/05/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

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

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of their knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials comply with the recipient's

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plan addressing compliance with the Dissemination of NIH-Funded Clinical Trial Information policy. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

Clinical Trial Study/Studies:
STUDY NUMBER: 427630

Risk Assessment
This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

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

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

Consortium
This award includes funds awarded for consortium activity with the following:
Mount Holyoke College
Stanford University

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01HD109320-02

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$110,268	$154,015	$154,015	$154,015
Fringe Benefits	$30,875	$43,124	$43,124	$43,124
Personnel Costs (Subtotal)	$141,143	$197,139	$197,139	$197,139

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Consultant Services	$4,275	$12,016	$12,016	$16,898
Travel		$1,878	$1,878	$3,755
Other	$3,717	$3,755	$3,755	$3,755
Subawards/Consortium/Contractual Costs	$266,213	$131,137	$120,544	$93,775
Equipment or Facility Rental/User Fees	$22,583	$34,409	$34,409	$34,409
TOTAL FEDERAL DC	$437,931	$380,334	$369,741	$349,731
TOTAL FEDERAL F&A	$39,687	$54,378	$54,378	$55,743
TOTAL COST	$477,618	$434,712	$424,119	$405,474

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	20.2%	20.2%	20.2%	20.2%
F&A Cost Base 1	$196,468	$269,197	$269,197	$275,956
F&A Costs 1	$39,687	$54,378	$54,378	$55,743

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/20/2024 12:18 AM

EXHIBIT C

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

Notice of Award
FAIN# R01HD109320
Federal Award Date
08/28/2024

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
[redacted]

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFR8QTK9H5M5

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD
[redacted]

8. Authorized Official
Kelly Blanchard
[redacted]

Federal Agency Information

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

10. Program Official Contact Information
Ronna Popkin

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

Federal Award Information

11. Award Number
3R01HD109320-02S1

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

15. Assistance Listing Number
93.865

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

17. Award Action Type
Supplement

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 05/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$59,000
20 a. Direct Cost Amount	$50,000
20 b. Indirect Cost Amount	$9,000
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$59,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$59,000
26. Project Period Start Date 09/21/2023 **– End Date** 05/31/2028	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,047,555

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Yvonne C. Talley

30. Remarks

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

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 3R01HD109320-02S1

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $59,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to IBIS REPRODUCTIVE HEALTH 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 R01HD109320. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Version: 25 - 2/15/2024 9:51 AM | Generated on: 8/28/2024 11:17 AM

Salaries and Wages	$7,018
Fringe Benefits	$1,965
Personnel Costs (Subtotal)	$8,983
Materials & Supplies	$809
Participant Subsistence	$40,208
Federal Direct Costs	$50,000
Federal F&A Costs	$9,000
Approved Budget	$59,000
Total Amount of Federal Funds Authorized (Federal Share)	$59,000
TOTAL FEDERAL AWARD AMOUNT	$59,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$59,000

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (2) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3R01HD109320-02S1	$59,000
5R01HD109320-02	$477,618
TOTAL	**$536,618**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$59,000	$536,618
3	$59,000	$493,712
4	$59,000	$483,119
5	$59,000	$464,474

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

Fiscal Information:
Payment System Identifier: 1030382773A1
Document Number: RHD109320A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024	2025	2026	2027
HD	8014702	$9,000	$59,000	$59,000	$59,000
OD	8025139	$50,000	$0	$0	$0

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**: 41023 / **Released**: 08/27/2024
Award Processed: 08/28/2024 11:17:42 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01HD109320-02S1

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 – 3R01HD109320-02S1

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

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

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

Office Of The Director, National Institutes Of Health (OD) Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD)

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

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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 – 3R01HD109320-02S1

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.

This award provides funding in the amount of **$59,000** to support Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality. **NICHD** will provide support in the amount of **$9,000** and **Sexual and Gender Minority Research Office (SGMRO)** will provide co-funding support in the amount of **$50,000.**

Human Subject

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".

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SPREADSHEET SUMMARY
AWARD NUMBER: 3R01HD109320-02S1

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$7,018	$13,964	$18,175	$25,122
Fringe Benefits	$1,965	$3,910	$5,089	$7,034
Personnel Costs (Subtotal)	$8,983			
Consultant Services				$9,950
Materials & Supplies	$809	$1,609	$2,094	$2,894
Travel		$2,000	$2,000	$5,000
Participant Subsistence	$40,208	$28,517	$22,642	
TOTAL FEDERAL DC	$50,000	$50,000	$50,000	$50,000
TOTAL FEDERAL F&A	$9,000	$9,000	$9,000	$9,000
TOTAL COST	$59,000	$59,000	$59,000	$59,000

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	18%	18%	18%	18%
F&A Cost Base 1	$50,000	$50,000	$50,000	$50,000
F&A Costs 1	$9,000	$9,000	$9,000	$9,000

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EXHIBIT D

National Institutes of Health
Office of Extramural Research

03/20/2025

Kelly Blanchard
IBIS REPRODUCTIVE HEALTH
[redacted]

Dear Kelly Blanchard:

Effective with the date of this letter, funding for Project Number 5R01HD109320-02 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 06/01/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

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

This award no longer effectuates agency priorities. Research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs. Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

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

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

Administrative Appeal

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

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

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

Sincerely,

Michelle G. Bulls, on behalf of Margaret Young, Chief Grants Management Officer,
National Institute of Child Health & Human Development
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

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

EXHIBIT E

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

Notice of Award
FAIN# R01HD109320
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
[redacted]

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFR8QTK9H5M5

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD
[redacted]

8. Authorized Official
Kelly Blanchard
[redacted]

Federal Agency Information

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

10. Program Official Contact Information
Ronna Popkin

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

Federal Award Information

11. Award Number
5R01HD109320-02

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

15. Assistance Listing Number
93.865

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

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

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$477,618
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$477,618
26. Project Period Start Date 09/21/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,047,555

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

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

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R01HD109320-02 REVISED

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to IBIS REPRODUCTIVE HEALTH 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 R01HD109320. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	$110,268

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Fringe Benefits	$30,875
Personnel Costs (Subtotal)	$141,143
Consultant Services	$4,275
Other	$3,717
Subawards/Consortium/Contractual Costs	$266,213
Equipment or Facility Rental/User Fees	$22,583
Federal Direct Costs	$437,931
Federal F&A Costs	$39,687
Approved Budget	$477,618
Total Amount of Federal Funds Authorized (Federal Share)	$477,618
TOTAL FEDERAL AWARD AMOUNT	$477,618
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (2) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01HD109320-02	$477,618
3R01HD109320-02S1	$59,000
TOTAL	**$536,618**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$477,618	$536,618

Fiscal Information:
Payment System Identifier: 1030382773A1
Document Number: RHD109320A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$427,618
OD	8055729	$50,000

NIH Administrative Data:
PCC: PDB -RP / **OC**: 41025 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:15:10 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD109320-02 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01HD109320-02 REVISED

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

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

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

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references cited above.)

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. 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*.

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

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

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

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) Office Of The Director, National Institutes Of Health (OD)

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 – 5R01HD109320-02 REVISED

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

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TERMINATION

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

CLOSEOUT

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

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.
- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

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

****

Funding Level
In accordance with NIH FY2024 fiscal policy, this non-competing award is reduced 1% below the committed funding level on the FY2023 Notice of Award. See NIH Guide Notice NOT-OD-24-109 for more information.

Co-fund
Co-funding support in the amount of $50,000 from the Office of Behavioral and Social Sciences Research (OBSSR).

Clinical Trial Terms

Dissemination Policy
The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application** dated **07/05/2022** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

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

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

Clinical Trial Study/Studies:
STUDY NUMBER: 427630

Risk Assessment

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This Clinical Trial Study or Studies listed above have been determined by NICHD to be considered **LOW** risk. Oversight by NICHD will occur in the standard manner through the annual RPPR. An annual update (no additional reports) on the status of the milestones included in Section 6 of the eRA HSS and any additional agreed-upon milestones are due in the RPPR. Information and procedures concerning these requirements are available on the NICHD Policies on Clinical Research site.

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Human Subjects

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

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

Consortium

This award includes funds awarded for consortium activity with the following:
Mount Holyoke College
Stanford University

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01HD109320-02 REVISED

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 2
Salaries and Wages	$110,268
Fringe Benefits	$30,875
Personnel Costs (Subtotal)	$141,143
Consultant Services	$4,275
Other	$3,717
Subawards/Consortium/Contractual Costs	$266,213
Equipment or Facility Rental/User Fees	$22,583
TOTAL FEDERAL DC	$437,931
TOTAL FEDERAL F&A	$39,687
TOTAL COST	$477,618

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	20.2%
F&A Cost Base 1	$196,468
F&A Costs 1	$39,687

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EXHIBIT F

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

Notice of Award
FAIN# R01HD109320
Federal Award Date
03/25/2025

Recipient Information

1. Recipient Name
IBIS REPRODUCTIVE HEALTH, INC.
[redacted]

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1030382773A1

4. Employer Identification Number (EIN)
030382773

5. Data Universal Numbering System (DUNS)
126940738

6. Recipient's Unique Entity Identifier
TFR8QTK9H5M5

7. Project Director or Principal Investigator
Heidi Serene Moseson Lidow, PHD
[redacted]

8. Authorized Official
Kelly Blanchard
[redacted]

Federal Agency Information

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

10. Program Official Contact Information
Ronna Popkin

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

Federal Award Information

11. Award Number
3R01HD109320-02S1

12. Unique Federal Award Identification Number (FAIN)
R01HD109320

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality

15. Assistance Listing Number
93.865

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

17. Award Action Type
Supplement (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 06/01/2024 **– End Date** 03/21/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$59,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$59,000
26. Project Period Start Date 09/21/2023 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,047,555

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Margaret A. Young

30. Remarks

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

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 3R01HD109320-02S1 REVISED

Principal Investigator(s):
Heidi Serene Moseson Lidow, PHD

Award e-mailed to: [redacted]

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to IBIS REPRODUCTIVE HEALTH 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 R01HD109320. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

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

Salaries and Wages	$7,018

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Fringe Benefits	$1,965
Personnel Costs (Subtotal)	$8,983
Materials & Supplies	$809
Participant Subsistence	$40,208
Federal Direct Costs	$50,000
Federal F&A Costs	$9,000
Approved Budget	$59,000
Total Amount of Federal Funds Authorized (Federal Share)	$59,000
TOTAL FEDERAL AWARD AMOUNT	$59,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (2) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
3R01HD109320-02S1	$59,000
5R01HD109320-02	$477,618
TOTAL	**$536,618**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$59,000	$536,618
3	$0	$434,712
4	$0	$424,119
5	$0	$405,474

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

Fiscal Information:
Payment System Identifier: 1030382773A1
Document Number: RHD109320A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
HD	8014702	$9,000
OD	8025139	$50,000

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**: 41023 / **Released**: 03/25/2025
Award Processed: 03/26/2025 12:14:52 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01HD109320-02S1 REVISED

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

SECTION III – STANDARD TERMS AND CONDITIONS – 3R01HD109320-02S1 REVISED

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

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

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e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) R01HD109320. 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:

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

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

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

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

Office Of The Director, National Institutes Of Health (OD) Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD)

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

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

TERMINATION

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

CLOSEOUT

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

The Closeout procedures should occur as expeditiously as possible while maintaining the safety of human subjects. There must be an orderly process to ensure the safety and welfare of participants. The grant close-out must occur within 120 days. The closeout will include:

- Informing all enrolled study participants of the study's termination and what study closure means for them:
    - Options pertaining to receiving further intervention, continuing follow-up, if required
    - Recognition of the value of their data and contribution to research
- If there remain participants that are actively participating in the research, the process and responsibilities will differ depending on the nature of the research.
    - If there is a prospect of direct benefit of the intervention and/or the intervention requires ongoing monitoring for safety and welfare there must be a plan to address these needs.
    - If there are no participants actively participating, or there is no need for ongoing monitoring or care, the protocol may be closed.
- Conduct any necessary final study visits or data collection procedures for enrolled participants.
- Notifying the IRB, DSMB, FDA, and/or other monitoring bodies of the study's closure.
- Assure all consent forms, case report forms, and source documentation for the study are completed as necessary and are present in the study files.
- Complete all adverse event reporting and reconciliation as per protocol.
- Perform any appropriate statistical analyses of the study data collected to date.
- Prepare a comprehensive final study report summarizing findings, including any deviations from the protocol and GCP compliance.
- Review and clean collected data for accuracy and completeness resulting in a locked dataset, suitable for sharing, as required.
- Confirm final disposition of investigational product(s) and devices. Plan for removal of any implanted devices, if applicable.
- Handle any biospecimens collected and prepare them for sharing, if required.

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- Update the study record and status to terminated in ClinicalTrials.gov as appropriate.

APPEALS

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

****

This award provides funding in the amount of **$59,000** to support Advancing novel survey tools to increase participation and improve sexual and reproductive health data quality. **NICHD** will provide support in the amount of **$9,000** and **Sexual and Gender Minority Research Office (SGMRO)** will provide co-funding support in the amount of **$50,000.**

Human Subject

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".

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01HD109320-02S1 REVISED

INSTITUTION: IBIS REPRODUCTIVE HEALTH

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$7,018			
Fringe Benefits	$1,965			
Personnel Costs (Subtotal)	$8,983			
Materials & Supplies	$809			
Participant Subsistence	$40,208			
TOTAL FEDERAL DC	$50,000			

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TOTAL FEDERAL F&A	$9,000			
TOTAL COST	$59,000	$0	$0	$0

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	18%			
F&A Cost Base 1	$50,000			
F&A Costs 1	$9,000			

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