National Institute of Environmental Health Sciences
Worker Training Program

Award Recipient Meeting

OCTOBER 22, 2024

RESEARCH TRIANGLE PARK, NC

The Plan

- Structure and Communication
- NIH Policy Updates
- Prior Approval Requests
- Reporting
- Other Support
- Offsets
- Clinical Trials

NIEHS Grants Management Structure

Chief Grants Management Officer (Jenny Greer) – responsible for the program in the context of the entire NIEHS grants portfolio; policy resource

Team Lead (Lisa Edwards) – responsible for the day-to-day management of the overall program; issues written guidance to the Grants Management Specialists assigned to the individual grants; addresses policy issues that affect all projects in the program

Grants Management Specialists (Camilo Asuncion, LaTavia Miller, Clark Phillips, and James Williams) – responsible for the day-to-day management of individual grants; resource for AOR/SO; address issues that affect individual grants

Grants Management Specialist assignments change from time to time – **check the Commons for your currently active grant**

Communication
NOT-OD-21-151

- **Business Office/Office of Sponsored Programs** - They are familiar with NIH policies **AND** with your institution's policies and procedures
- **Administrative Questions** – The Signing Official (Not the PI) should contact the assigned Grants Management Specialist
  - ALWAYS include the grant number in all correspondence
- **Scientific/Programmatic Questions** - Contact the designated Program Officer
- **Review Questions** - Contact the Scientific Review Officer listed in the Notice of Funding Opportunity (NOFO)

NIH Data Management and Sharing Policy

Beginning January 25, 2023, competing applications involving generation of scientific data must include a DMS Plan

- Implementation Details for the NIH Data Management and Sharing Policy (NOT-OD-22-189)
- Prior Approval Requests for Revisions to an Approved Data Management and Sharing (DMS) Plan Must be Submitted Using the Prior Approval Module (NOT-OD-23-185)
- **Reporting Data Management and Sharing (DMS) Plan Activities in the Research Performance Progress Report (RPPR) (NOT-OD-24-123)**

Inbox for Inquiries Related to Federal Financial Reports (FFRs) and Financial Closeout

NOT-OD-23-035

December 5, 2022

A central email inbox for inquiries related to the submission and processing of Federal Financial Reports (FFRs) and financial closeout has been established by the Office of Policy for Extramural Research Administration (OPERA) FFR Reconciliation and Financial Closeout Support Center at OPERAFFRInquiries@od.nih.gov

Disaster Policy

Assistance to the NIH community during natural disasters is handled on a case-by-case basis in a manner appropriate to the circumstances.

For major disasters impacting many institutions, NIH will coordinate with other Federal agencies (such as HHS, FEMA and OMB), as well as with state, local, and institutional representatives, to develop any additional response. NIH will consider such issues as whether a Federal Disaster is declared; the severity of damage inflicted; the length of time an institution may be required to close or that is required for recovery; the impact on investigators, human research subjects, and animal subjects; and the overall impact on the community. A list of possible actions NIH may take are listed below. Please note that these steps are not automatic but will be announced as appropriate on this web page and in the NIH Guide for Grants and Contracts.

- Permitting the limited expenditure of award funds, in accordance with recipient policy, to continue paying salaries and fringe benefits to researchers under unexpected or extraordinary circumstances.
- Assisting with animal welfare issues.
- Waiving certain prior approval requirements.
- Providing extensions of time for financial and other reporting.
- Publishing opportunities for funded extensions and/or one-time administrative supplements to current awards targeted at institutions in particularly impacted areas.

https://grants.nih.gov/policy-and-compliance/policy-topics/natural-disasters

Policy Update Resources

- NIH Policy Changes website

https://grants.nih.gov/policy/notices.htm

- To subscribe to receive NIH Policy Updates
  https://grants.nih.gov/grants/guide/listserv_dev.htm

Prior Approvals

Carryover

- Carryover should only be requested when current year funds have been committed and there is a bona fide need for prior year funds
- Before requesting carryover, check your Notice of Award to see if there has been an offset applied. Funds used to offset your award are not available for you to carry over.
- Supplements that have been awarded to the grant are generally eligible for carryover into the next budget period.

Change of Principal Investigator (PI) or Key Personnel (KP)

- This is a **Prior** Approval action, and a formal request must be submitted by the Signing Official to the assigned Grants Management Specialist **before** the change occurs.
- Only the Signing Official can initiate and submit a Change of PI or KP
- NIH approval comes through a revised Notice of Award.

Reporting

Annual Federal Financial Report (FFR)

FFRs must be submitted each BUDGET period 90 days after the end of the calendar quarter in which the budget period ends.

- U45 - Budget period end is 5/31 with a FFR due date around 9/30

  (Thank you all have been submitted except for 1)

- UH4 - Budget period end is 7/31 with a FFR due date around 12/31

  (Thank you all were submitted on time last year)

Final Federal Financial Report

Due 120 days after the project period end date

Other Support

Other Support

Must include:

- **all** resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant
- All current and pending support
- Total award amount (including indirect costs) for each project
- In-kind contributions (if not contributing to the grant for which the application has been submitted)
- Electronic signature
- Copies of contracts, grants, other agreements for foreign (in English)

Other Support Review

- Commitment Overlap – does total effort exceed 12 calendar months for any individual?
- Budgetary Overlap – is the recipient receiving funding from multiple sources for the same work?
- Scientific Overlap – are there projects on the other support document that appear to duplicate the scientific aims of the project under consideration?

All forms of overlap must be resolved prior to award

Other Support Resources

- NIH Other Support https://grants.nih.gov/grants/forms/othersupport.htm
- NIH Other Support FAQs - https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm
- Other Support Format Page https://grants.nih.gov/sites/default/files/other-support-format-page-rev-10-2021.docx
- NIH Pre-Award and Post-Award Disclosures https://grants.nih.gov/grants/forms/NIH-Disclosures-Table.pdf
- NIH Other Support Training – Video (https://youtu.be/Xn2MLfO1jqU) and PowerPoint (https://grants.nih.gov/sites/default/files/slideset-Commitment-Transparency-Nov2021.pptx)

Offsets

FY2025 Strategy – Offsetting

- Authorizes the use of funds from a previous project period in the new project period
- Applicable to the 1st noncompeting award (T5) after a renewal (T2)
- Does not change the current budget period authorized amount of funding but does reduce the amount of current fiscal year funds provided to support the authorized award amount.

Rationale: At the completion of a competitive phase and initiation of a new competitive phase (type 2 application) the work of the original phase is complete, and the work planned for the new phase is supported by the specific aims and budget from the new award.

Offset on the Notice of Award

Summary Federal Award Financial Information

19. Budget Period Start Date 08/15/2024 – **End Date** 06/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$466,707
20 a. Direct Cost Amount	$505,735
20 b. Indirect Cost Amount	$30,668
21. Authorized Carryover	$0
22. Offset	$69,696
23. Total Amount of Federal Funds Obligated this budget period	$466,707
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$466,707

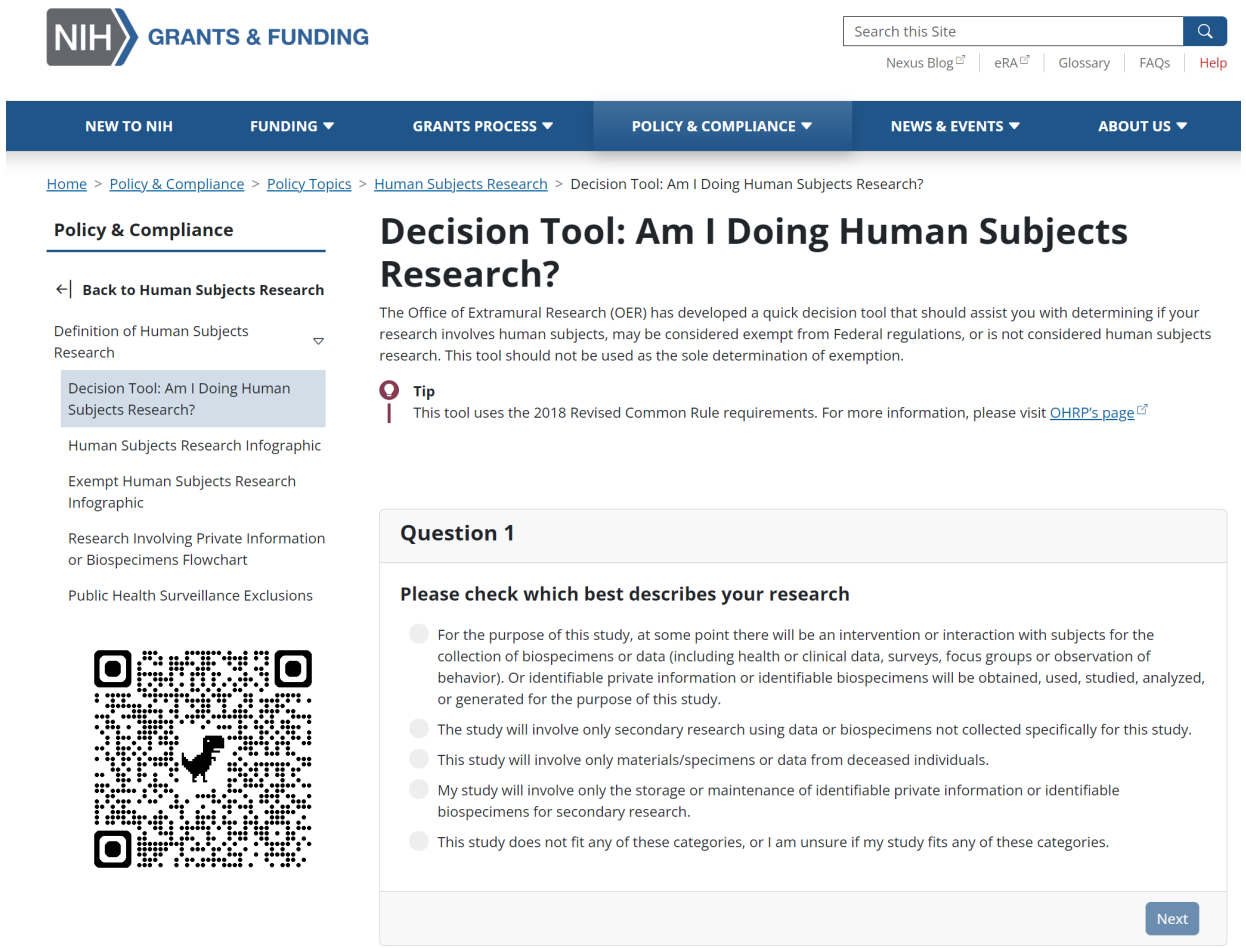
Federal Direct Costs	$505,735
Federal F&A Costs	$30,668
Approved Budget	$536,403
Total Amount of Federal Funds Authorized (Federal Share)	$466,707
Cumulative Authorized Carryover and Offset for this Budget Period	$69,696
TOTAL FEDERAL AWARD AMOUNT	$466,707
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$466,707

Carryover

Carryovers from one project period into the next project period may not exceed 25% of the T2 award

Human Subjects & Clinical Trials

Is the Project Human Subjects Research?



Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Examples of human subjects research include:

- Collecting blood
- Conducting a survey
- Changing participants' environment
- Administering medicine
- Interviewing
- Administering a psychological test
- Collecting data
- Conducting a focus group
- Testing a new educational technique

Included in the NIH application:

✓ Protection of Human Subjects attachment

If funded, grantees will need:

✓ An Institutional Federal-Wide Assurance (FWA) with OHRP

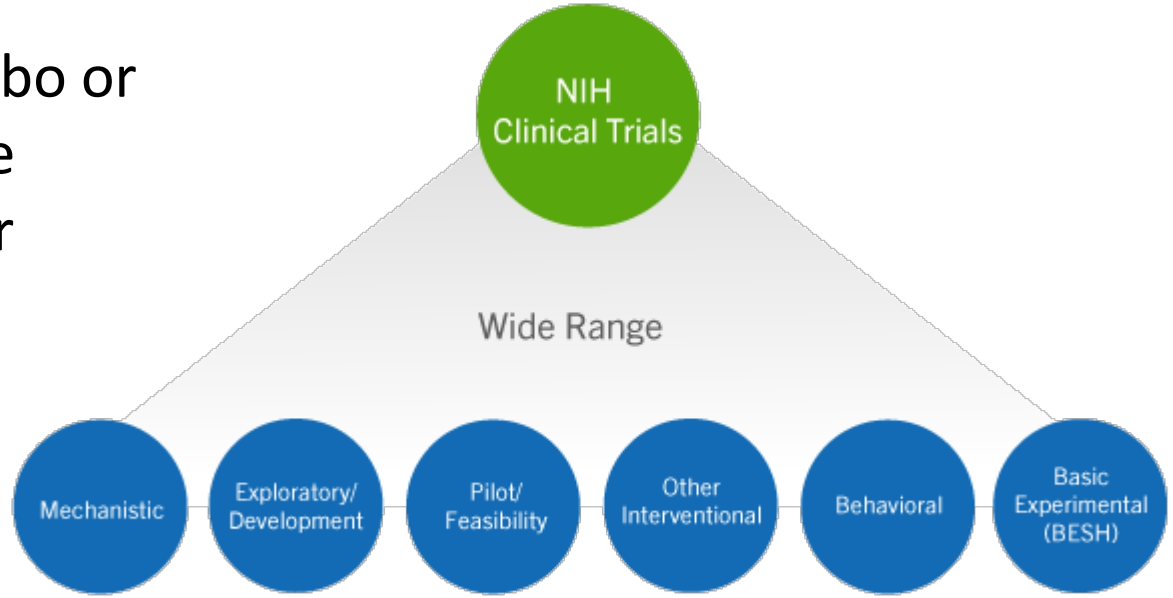
✓ IRB approval or determination of exemption

✓ Human Subjects education* even for exemptions

NIH Definition of Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

NOT-OD-15-015



The 4 CT Questions

- Does the study involve **human participants**?
- Are the participants **prospectively assigned** to an **intervention**?
- Is the study designed to **evaluate the effect** of the intervention on the participants?
- Is the effect that will be evaluated a **health-related biomedical or behavioral outcome**?

If "Yes" to ALL of these questions, the study is considered a clinical trial

NOT-OD-15-015

Prospectively assigned refers to a pre-defined process (e.g., randomization) in the assignment of research subjects (individually or in clusters) to one or more groups.

Intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and positive or negative changes to quality of life.

Resources:

NIH National Institutes of Health
Office of Extramural Research

Division of Human Subjects Research (DHSR)
Resources on Human Subjects, Clinical Trials, and Inclusion

For a more comprehensive resource list, visit the *Resources* section of the Human Subjects Research Training and Resources website.

Human Subjects

Websites
- Human Subjects Protections website
- Single IRB website
- Certificates of Confidentiality website

Tools and Media
- Decision Tool: Am I Doing Human Subjects Research?
- Flowchart: Research Involving Private Information or Biospecimens
- Infographic: Exempt Human Subjects Research
- Human Subjects Protection and Monitoring Podcasts: Am I Doing Human Subjects Research Podcast, Human Subjects Protection and Monitoring Plans, and Human Subjects Research Post-Award

Training
- Overview of NIH Policies on Human Subjects recording, transcript, and slide set

Clinical Trials

Websites
- Clinical Trial Requirements website and Frequently Asked Clinical Trial Questions (FAQs)
- Basic Experimental Studies Involving Humans (BESH) website

Tools and Media
- Clinical Trial Decision Tool
- Clinical Trial Case Studies

Training
- An Overview of NIH Policies on Clinical Trials video, transcript, and slide set
- Basic Experimental Studies Involving Humans (BESH) podcast and transcript

Inclusion

Websites
- Inclusion Policies website, Inclusion of Women and Minorities Policy FAQs, and Inclusion Across the Lifespan Policy FAQs

Tools and Media
- Recruitment and Retention Resource List
- Tip Sheet: Using the Participant-level Data Template

Training
- Including Diverse Populations in NIH-Funded Clinical Research video and video transcript

Last updated 8/24/2023

https://grants.nih.gov/sites/default/files/DHSR-HS-CT-Inclusion-External.pdf

Questions

Jenny Greer
Chief Grants Management Officer
jenny.greer@nih.gov

Lisa Edwards
Lead Grants Management Officer
984-287-3258
archer@nih.gov

Michelle Campbell
Human Subjects Research Subject Matter Expert
984-287-3972
campbel5@niehs.nih.gov