FY2025 NOFO Technical Assistance Webinar: Ensuring Research Integrity

Health and Human Services Office of Research Integrity

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Webinar Agenda

- Programmatic Overview of the Notice of Funding Opportunities (NOFOs)
 - IR-ORI-25-001
 - IR-ORI-25-002
 - IR-ORI-25-003
- Grants and Acquisitions Management
 - Competitive application requirements and process



Programmatic Overview

- ORI's Mission
 - Promote Research Integrity
 - Prevent Research Misconduct
 - Protect Science, Public Health, and Public Health Service (PHS) funds



IR-ORI-25-001: Ensuring Research Integrity - Research on Research Integrity (RRI)

• Purpose: To promote the integrity and reliability of PHS-funded research through empirical research on societal, organizational, behavioral, group, and individual factors that affect, both positively and negatively, integrity in research with a focus on the identification of the root causes of research misconduct and driving factors for research integrity in compliance with 42 C.F.R Part 93.



IR-ORI-25-001: Ensuring Research Integrity - Research on Research Integrity (RRI)

We have selected the following three focus areas for Fiscal Year 2025:

1) Explore the financial, cultural, institutional, and individual factors

- Studying the impact of institutional culture on research practices and misconduct
- Studying the day-to-day policies and procedures, such as record keeping, experimental design, bias reducing techniques, and data sharing in research institutions and their impact on research misconduct

2) Assess the effectiveness of policies and training

- Conducting randomized controlled trials to test the impact of training programs on researchers' understanding and application of ethical standards as well as social responsibility
- Analyzing longitudinal data to evaluate the long-term effects of policy changes on research integrity

3) Investigate reporting and response mechanisms

- Researching the effectiveness of different institutional responses to allegations of misconduct and their impact on deterring future issues
- Studying the psychological barriers to reporting misconduct and develop strategies to overcome them



Award Information

- **Type of Award**: Grant
- Anticipated Number of Awards: 1-2
- Anticipated Start Date: September 30, 2025
- Award Amount (Federal Funds + indirect costs): YR 1: up to \$250,000 per budget period; YR 2: up to \$375,000 per budget period
- Estimated Period of Performance: Not to exceed 2 years
- Anticipated Initial Budget Period Length: 12 months



IR-ORI-25-002: Ensuring Research Integrity - Conferences and Workshops Program (CWP)

 Purpose: to provide assistance for those concerned with research integrity to meet to discuss theoretical, empirical, research design, educational, legal, procedural, ethical, and other aspects related to promoting the responsible conduct of research, preventing research misconduct, and/or addressing issues that arise after an allegation of research misconduct is brought forward at an institution.



IR-ORI-25-002: Ensuring Research Integrity - Conferences and Workshops Program (CWP)

Projects must belong to one of the following priority areas:

- 1) Organization of thematic conferences:
 - Hosting events that bring together interdisciplinary experts to address specific challenges in research integrity, such as data sharing or dualuse research
 - Workshops focusing on the development of international standards for research integrity

2) Skill-Building Workshops:

- Conducting hands-on workshops where participants can learn about and practice implementing new tools or strategies to promote integrity in research
- Training sessions for research integrity officers on handling allegations of research misconduct in accordance with 42 C.F.R. Part 93
- Workshops for institutional officials involved in writing implementing policies and procedures for handling allegations of research misconduct

3) Outreach and Education Events:

- Public symposia aimed at engaging the wider community in discussions about the importance of research integrity
- Public forum where researchers are given a platform to discuss the potential drivers that influence research misconduct
- Webinar series featuring leading experts discussing recent developments and emerging issues in the field of research integrity



Award Information

- **Type of Award**: Grant
- Anticipated Number of Awards: 1-2
- Anticipated Start Date: September 30, 2025
- Award Amount (Federal Funds + indirect costs): YR 1: up to \$50,000
- Estimated Period of Performance: Not to exceed 12 months
- Anticipated Initial Budget Period Length: 12 months



IR-ORI-25-003: Ensuring Research Integrity - Program Development and Evaluation Program (PDE)

Purpose: to promote the development and implementation of innovative programs and tools for (a) fostering research integrity; (b) preventing or detecting research misconduct; (c) protecting whistleblowers, respondents, and other vulnerable researchers; and (d) enabling the proper handling of research misconduct allegations.



IR-ORI-25-003: Ensuring Research Integrity – Program Development and Evaluation Program (PDE)

This program supports the creation and evaluation of interventions and assessment tools aimed at promoting research integrity. Projects may include:

1. Development of Educational Resources:

- Creation of novel online training modules incorporating interactive scenarios to teach principles of research integrity
- Development of engaging, in-person or classroom educational programs that promote the responsible conduct of research, prevent research misconduct, or encourages the reporting of suspected research misconduct

2. Creation of Risk Assessment Tools:

- Design, develop, and test assessment tools for principal investigators, department chairs, or other research administrators to evaluate the risk for individuals, laboratories, or research programs to engage in misconduct or detrimental research practices
- Design, develop, and test assessment tool that examines institutional research culture or practices that impact or lead to potential research misconduct

3. Implementation and Testing of Intervention Programs:

- Pilot interventions designed to improve data management and record-keeping in labs, with pre- and post-assessment of research integrity
- Implementation of mentorship and leadership training programs in research



Award Information

- **Type of Award**: Grant
- Anticipated Number of Awards: 1-2
- Anticipated Start Date: September 30, 2025
- Award Amount (Federal Funds + indirect costs): YR 1: up to \$75,000
- Estimated Period of Performance: Not to exceed 12 months
- Anticipated Initial Budget Period Length: 12 months



Submission Dates and Times

- Application is due by 6:00 p.m. Eastern Time, Wednesday, July 30, 2025
- Your submission time will be determined by the date and time stamp provided by Grants.gov when you
 complete your submission
- Strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date
- Grants.gov may take up to 48 hours to notify you of a successful submission
- If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration



Address to Request Application Package

- Obtain an application package electronically by accessing Grants.gov at <u>http://www.grants.gov/.</u>
 Find it by searching the Assistance Listing (formerly CFDA) Number found on page 2 of the NOFO
- The Assistance Listing (CFDA) Number is 93.085
- Be sure to subscribe to the announcement in Grants.gov so you receive notification of any updates to the NOFO or supporting documents



Eligible Applicants

- Applicant eligibility for this NOFO is:
 - ✓ Universities, hospitals, laboratories, other public or private institutions, and individuals
 - Any public or private entity, including faith-based, community-based, and Indian Tribes or Tribal organizations
 - ✓ American Indian, Alaska Native, Native Hawaiian, and Pacific Islander organizations
- Foreign entities are NOT eligible



Application Responsiveness Criteria

- We will review your application to determine whether it meets the responsiveness criterion in Section F.1
- If your application does not meet the responsiveness criterion, we will disqualify it from the competition; we will not review it beyond the initial screening



Cost Sharing or Matching

- You are not required to provide cost sharing or matching in your proposed budget
- If you voluntarily include cost sharing in your application, you must include in your budget narrative a non-federal sources justification. During the merit review of an application, cost sharing will only be considered in the overall review of the adequacy of the total proposed budget (Federal and non-Federal share) to support the project proposed
- Applications including voluntary cost sharing or matching that result in an award will include the cost sharing or matching commitment on the notice of award at the level proposed in the application. Any change in that commitment will require prior approval of the Grants Management Officer



Application Submission

- OASH requires that all applications be submitted electronically via Grants.gov unless an exemption has been granted by the grants management officer
 - If you submit an application via any other electronic communication, it will not be accepted for review
 - Grants.gov is a website portal. All funding opportunities and grant application packages are made available on <u>www.Grants.gov</u>
 - An application will not be considered valid until all application components are entered in Grants.gov and received by HHS Office of Grants and Acquisitions Management according to the deadlines specified in the "DATES" section of the NOFO
 - Contact Grants.gov with any questions or concerns regarding the electronic application process



Application Submission (continued)

• Applications must be submitted as three (3) files:

File 1: The ENTIRE project narrative

File 2: The ENTIRE budget narrative, including supporting documentation described in the Budget Narrative content section

File 3: All documents in the appendices uploaded in the Attachments section of your Grants.gov application

Note: required standard forms do not apply toward your page count limitations in the submission requirements as stated in Disqualification Criteria.



Application Submission (continued)

- Any files uploaded or attached to the Grants.gov application must be of the following file formats
 - Microsoft Word, PowerPoint, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only)
 - Microsoft Excel files, compressed files, and password protected files will NOT be accepted
- HHS/OASH strongly recommends that electronic applications be uploaded as Adobe PDF
 - If you convert to PDF prior to submission, you may prevent any unintentional formatting that might occur with submission of an editable document
- Check your page count of the PDF and/or print your file to ensure that the document does not exceed the page limits



Application Submission (continued)

- Be complete and do not leave blanks on forms unless the information is clearly not applicable
- The individual submitting the application forms must have the legal authority to act on behalf of the organization
- To ensure successful submission of your application, carefully follow the step-by-step instructions provided at https://www.grants.gov/applicants/grant-applications/how-toapply-for-grants
- These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information



Application Elements

Forms:

- Application for Federal Assistance (SF-424)
- Budget Information for Non-construction Programs (SF-424A)
- Disclosure of Lobbying Activities (SF-LLL)
- Project Abstract Summary

Files:

- Project Narrative Submit all Project Narrative content as a single acceptable file
- Budget Narrative Submit all Budget Narrative content as a single acceptable file
- Appendices Submit all appendix content as a single acceptable file, in the Attachments section
 of your Grants.gov application



Application Format

- Be sure to follow Project Narrative format instructions in the NOFO. Your application will be disqualified if it does not conform to the format requirements:
- You must double-space the Project Narrative pages
- You must use 12-point font
- You should use an easily readable typeface, such as Times New Roman or Arial
- You may single-space tables or use alternate fonts but you must ensure the tables are easy to read
- For Appendices and Budget Narrative, you should use the same formatting specified for the Project Narrative
- Appendix documents such as résumés may use alternate formats common to such documents



System for Award Management (SAM)

- If you are registering a <u>new</u> entity in SAM.gov, you need to create a login.gov account, if you don't already have one
 - Please note that the complete process for registering a new entity involves submission of a notarized letter by mail.
- If you are renewing your registration, your old SAM.gov username and password will not work anymore. You will need to create a login.gov account if you do not already have one
- Minimum timeframe to complete an initial SAM registration online is 30 min
- Timeframe for applicant's registration to become active is up to 10 days and may take longer depending on volume
- SAM registration <u>must</u> be renewed each year
- Average timeframe for updates in SAM.gov to appear in Grants.gov is up to 72hrs



SAM (continued)

- We strongly recommend applicants check for an active registration in SAM well before application deadline
- If you are successful and receive an award, you must maintain an active SAM registration with current information **at all times** during the active award
- If you have not complied with the SAM registration requirements, HHS/OASH
 - May determine you are not qualified to receive an award; and
 - May use that determination as a basis for making an award to another applicant
- Should you successfully compete and receive an award, all first-tier sub-award recipients must have a UEI(SAM) number at the time you, the recipient, make a sub-award



Unique Entity Identifier (UEI)

- You are required to provide a Unique Entity Identifier (UEI) number when applying for Federal awards through Grants.gov
 - It is a unique, 12-character alphanumeric identifier assigned to all entities to do business with the Federal Government
 - You will find instructions on the Grants.gov website as part of the organization registration process at https://grants.gov/applicants/applicant-registration/



Funding Restrictions

- If you are successful and receive an award, by accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions
- Costs must be allowable, allocable, reasonable, and necessary direct expenses or indirect costs in accordance with regulations and current policy
- Indirect costs may be included per 45 CFR 75.414. Applicants should indicate which method or rate is used for this
 application
- Pre-award costs are not allowed
- Current Salary Limitation: \$225,700 effective January 2025



Budget Narrative and Forms

The Project Budget Information:

- SF 424A Budget Forms
- Budget Narrative
- Detailed Budget Justification
- Must be consistent with the requirements of the NOFO
- Budgeted costs must reflect proposed activities
- Budget line item descriptions and justification requirements are explained in the NOFO
- Suggested table formats in the NOFO
- Plan for Oversight of Federal Award Funds Forms, narrative and detailed justification do not count toward page limit



Application Disqualification Criteria

If you application does not meet the following requirements it will be disqualified and receive no further consideration:

- Submitted electronically via www.grants.gov by due date and time (unless an exemption was granted 2 business days prior to the deadline)
- If you successfully submit multiple applications for the same project, we will only review the last application received by the deadline
- HHS/OASH/GAM deems your application eligible
- Project Narrative must be double-spaced, on the equivalent of 8.5" X 11" page size with 1" margins on all sides and font size not less than 12 points
- Project Narrative must not exceed 30 pages
- The Total Application, including Project Narrative must not exceed 75 pages



Application Disqualification Criteria (continued)

- If you application does not meet the following requirements it will be disqualified and receive no further consideration:
 - Your application must be in the English language and must be in terms of U.S. dollars (45 C.F.R. 75.111(a))
 - Your Federal funds request including indirect costs does not exceed the maximum indicated in Award Ceiling.
 - If you have included voluntary cost sharing or matching, you must include in your budget narrative a non-federal sources justification
 - Application meets the Application Responsiveness Criteria



Supporting Documentation and Disqualification

- Applications that lack the required supporting documentation or submit additional appendix files will not be disqualified from competitive review;
- However, this may impact your application's rating under the evaluation criteria
- Be sure to follow submission instructions carefully



Application Review Criteria

Equally weighted criteria:

- Project Description
- Outcomes, Evaluation, and Dissemination
- **Project Management and Environment and Organizational Capability**



Application Merit Review

- Eligible applications will be reviewed and rated by a panel of independent reviewers with technical expertise in applicable fields according to the criteria listed in the NOFO
- The Merit Review Panel process is formal and confidential. Federal staff are available for questions and to ensure the process is consistent and fair, but do not participate in discussion and scoring
- Applications are then also reviewed:
 - By GAM staff for administrative & business compliance
 - ✓ By ORI Program Office staff for programmatic compliance



Funding Decisions

- The Director of the Office of Research Integrity will make final award selections to be recommended to the Grants Management Officer for risk analysis
- Upon completion of risk analysis and concurrence of the Grants Management Officer, HHS/OASH will then issue Notices of Award
- No award decision is final until a Notice of Award is issued
- All award decisions, including level of funding, if an award is made, are final and you may not appeal



Funding Process

- We are not obligated to make any Federal award as a result of this announcement
- Only the grants officer can bind the Federal government to the expenditure of funds
- If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration



Funding Process – Review of Risk Posed by Applicant

- HHS/OASH will evaluate each application in the fundable range for risks posed by the applicant before issuing an award in accordance with 45 CFR 75.205
- OASH will use a risk-based approach and may consider any items such as the following as stated in the NOFO:
 - ✓ Applicant's financial stability;
 - ✓ Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;
 - History of performance Applicant's record in managing Federal awards including timeliness of compliance with applicable reporting requirement, and conformance to the terms and conditions of previous Federal awards;
 - ✓ Reports and findings from audits performed; and
 - The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities



Risk Review Resulting in Non-funded Determination

- If we determine your organization does not meet either or both minimum qualification standards as described in 45 CFR §75.205(a)(2) and we do not make an award to you as a result, we must report that determination to SAM, if certain conditions apply
- The standards include at a minimum, if you are a prior Federal award recipient the information in SAM must "demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics." 45 CFR § 75.205(a)(2)
- Information reported in SAM is available for other organizations to review when considering you for an award



Notice of Award (NOA)

The Notice of Award:

- Notifies the successful applicant of the selection; award amount; project and budget periods
- Includes any conditions on the award (i.e., requirements that must be met as a condition of receiving the grant funds)
- Includes standard terms, reporting requirements and contact information for OASH/GAM and the Program Office



Funding Process – Points of Contact

- GAM is the official contact for awardees throughout the award life cycle
- All official communication related to the award is between GAM and the successful applicant
- Unsuccessful applicants will be notified by Program Office via letter
- Note While GAM is the official contact, program should be notified of any changes



Project Narrative Description:

- Be clear, complete and concise in the project description; follow and address exactly what is requested in the NOFO
- Don't make the reviewer search for the required information. Generally, the easier the application is to review, the better the rating
- Reviewers are not allowed to do external research, follow embedded links, etc.
- Clearly identify the sections of the application and indicate which component is being addressed
- The project narrative must include all required information within the page limit. Do not use appendices to expand the page limit.



Project Narrative Description:

- Make the goals and objectives "SMART;" Specific; Measurable; Achievable; Realistic; and Timeframed
- Activities presented in the work plan should relate directly to the proposed goals and objectives
- The program work plan, evaluation plan and budget should provide a complete picture of how the applicant will address the needs as well as address the purpose and expectations in the NOFO



Staffing:

- The staffing should be appropriate and reasonable for the goals, objectives and activities of the proposed project
- Be complete in describing what staff will do, the expertise required, and the percent time they will be assigned to the project



Budget:

- The budget should include adequate funds to carry out the proposed work plan, evaluation plan and administrative responsibilities of the project
- The budget should be reasonable and relate directly to the goals and objectives
- Do not request more funds than are available, as listed in the NOFO. This amount is *inclusive* of indirect costs
- The operating budget should be complete and include Federal and non-Federal funds, projected program income from fees and third party payers and other contributing funds



Overall:

- Include full names (<u>First Middle Last</u>) for Authorized Official, Principal Investigator/Project Director and all Essential Personnel
- Electronic submission <u>IS</u> required
- Do not wait until the last minute to begin SAM registration or update your registration
- Do not wait until the last minute to begin the electronic submission— problems could arise



NOFO Inquiries

<u>Program Questions</u> \rightarrow Office of Research Integrity (ORI)

Armineh Ghazarian, MS, MSF

Email: <u>Armineh.Ghazarian@hhs.gov</u>

Administrative or Financial Questions \rightarrow Grants Management Specialist: Jessica Shields

Email: <u>Jessica.Shields@hhs.gov</u>

Telephone: 240-453-8822

Electronic Submission Requirements Grants.gov Applicant Support

Email: <u>support@grants.gov</u> Telephone: 800-518-4726

Please DO NOT contact OASH Program or Grants office staff for Grants.gov issues



Contact ORI: ORIgrants@HHS.gov

Connect with us: X: <u>@HHS_ORI</u> Youtube: <u>@HHS_ORI</u>

Visit ORI: ORI.HHS.gov

