

FY2021 NOFO Technical Assistance Webinar: Considerations, Options, and Resources for Data Management in PHS Funded Research

IR-ORI-21-001

Thursday, May 6, 2021



OASH

Office of the
Assistant Secretary
for Health

Webinar Agenda

- Programmatic Overview of the Notice of Funding Opportunity (NOFO)
- Grants and Acquisitions Management
 - Competitive Application Requirements and Process
- Question and Answer Session

Programmatic Overview

ORI's Mission:

- Promote Research Integrity
- Prevent Research Misconduct
- Protect Science, Public Health, and Public Health Service (PHS) Funds

Programmatic Overview (continued)

- ORI's Research on Research Integrity assistance program contributes to this mission by supporting projects that advance the evolving field of research integrity and build the knowledge base in research misconduct, research integrity, and prevention.
- Responsible management of data throughout the research lifecycle is key to ensuring the integrity, reliability, and availability of data acquired in connection with PHS-funded research.

Purpose (Executive Summary, page 2)

This notice solicits applications for projects that: 1) conduct research on responsible data management and stewardship approaches and practices; and, based on the results of this research, 2) develop practical approaches, considerations, and resources that can be directly implemented by researchers, research institutions, and research administrators.

Focus Area (Executive Summary, page 3)

The goal of this funding opportunity is to support the development of approaches and resources for data management and stewardship (which also includes data storage and retention of an array of data types) that will help enhance the integrity and reliability of data generated with Public Health Service (PHS) funds, ensure data acquired using PHS funds are available for subsequent use by the research community, and ensure data are available for examination should there be an issue related to the integrity, authenticity, reproducibility, and/or reliability of the research.

Award Information (Section D, page 13)

- Estimated Federal Funds Available: \$600,000
- Anticipated Number of Awards: 1
- Award Amount (Federal Funds including indirect costs): up to \$600,000 per budget period
- Anticipated Start Date: September 1, 2021
- Estimated Period of Performance: Not to exceed 2 years
- Anticipated Initial Budget Period Length: 24 months
- Type of Award: Cooperative Agreement

Program Description - Expectations (Section B.2, pages 7 - 11)

- a. Conduct research to identify and assess existing practices and needs as related to research data management and stewardship.
- b. Disseminate research findings and obtain feedback on these findings and future directions from stakeholders in the PHS-funded research community.
- c. Develop, based on the results of the research and feedback described above, practical approaches, considerations, and resources that can be directly implemented by researchers, research administrators, and research institutions to enhance data management and stewardship practices throughout the research lifecycle.
- d. Disseminate and distribute the information, resources, and materials developed under the auspices of this cooperative agreement.

Program Description - Expectations (Section B.2.a, pages 7 - 9)

- a. Conduct research to identify and assess existing practices and needs as related to research data management and stewardship.
 - ORI expects that research and assessment activities will focus on practices, approaches, and needs, related to data management and stewardship, at the level of the researcher, research administrator, and research institution throughout the research lifecycle.
 - Results from these activities are expected to support and inform the development of approaches, considerations, and resources that can be adopted for use across the broad spectrum of biomedical research funded by the PHS.

Program Description - Expectations (Section B.2.a, pages 7 - 9, continued)

- a. Conduct research to identify and assess existing practices and needs as related to research data management and stewardship.
 - It is expected that practices and approaches related to the following eight topics will be researched and examined.
 - 1) Provenance
 - 2) Recordkeeping
 - 3) Organization of data
 - 4) Storage of data
 - 5) Reporting of research data and results
 - 6) Sharing and Access
 - 7) Institutional Policies
 - 8) Data Management Standard Operating Procedures
 - Additionally, it is expected that the needs of researchers, research administrators, and research institutions, related to each topic, will be assessed.

Program Description - Expectations (Section B.2.b, page 9)

- b. Disseminate research findings and obtain feedback on these findings and future directions from stakeholders in the PHS-funded research community.
 - ORI expects that results from, and future directions informed by, the research and assessment activities conducted above will be presented to stakeholders in the PHS-funded research community for discussion and feedback.
 - ORI expects that, as relevant, feedback from the PHS-funded research community will be considered and used to refine plans for resource development activities in part c. below.
 - Plans for sharing research findings with and obtaining feedback from stakeholders in the PHS-funded research community are expected to support project goals and timely progress of the overall project.

Program Description - Expectations (Section B.2.c, page 10)

- c. Develop, based on the results of the research and feedback described above, practical approaches, considerations, and resources that can be directly implemented by researchers, research administrators, and research institutions to enhance data management and stewardship practices throughout the research lifecycle.
 - ORI expects that practical resources, approaches, and considerations will be developed, based on the research conducted above and informed by feedback from stakeholders in the PHS-funded research community, to address the needs identified for each of the eight topic areas above.

Program Description - Expectations (Section B.2.c, page 10, continued 2 of 3)

- c. Develop, based on the results of the research and feedback described above, practical approaches, considerations, and resources that can be directly implemented by researchers, research administrators, and research institutions to enhance data management and stewardship practices throughout the research lifecycle.
- The materials should be designed and developed such that they can be readily adapted for the specific research discipline, if necessary, but otherwise directly used or implemented to facilitate responsible data management and stewardship practices at the level of the relevant stakeholder. All materials should be designed with ease of use and implementation for the end user in mind.

Program Description - Expectations (Section B.2.c, page 10, continued 3 of 3)

- c. Develop, based on the results of the research and feedback described above, practical approaches, considerations, and resources that can be directly implemented by researchers, research administrators, and research institutions to enhance data management and stewardship practices throughout the research lifecycle.
 - ORI also expects that all print materials will be available in commonly readable formats that are most appropriate for the intended use.

Program Description - Expectations (Section B.2.d, page 11)

- d. Disseminate and distribute the information, resources, and materials developed under the auspices of this cooperative agreement.
- ORI expects that researchers, research administrators, and research institutions will be made aware of the availability of and given access to the materials developed above.
 - ORI expects the development and implementation of a comprehensive dissemination plan to communicate key findings to stakeholders, the general public, and other parties who might be interested in the results of the proposed project.
 - The plan is expected to include a description of the method that will be used to disseminate the project's results and findings in a timely manner.

Program Description - Substantial Program Involvement (Section B.3, pages 11 - 12)

- This award is a cooperative agreement.
- Cooperative agreements are a form of assistance that allows for substantial involvement between ORI and the recipient during the project period.
- ORI substantial programmatic involvement may include:
 - Serving as a resource to provide programmatic support during the implementation of the project by participating in the design of the activities and contributing with subject matter expertise.
 - Assisting the awardee to establish, review, and update priorities for activities conducted under the auspices of this cooperative agreement.
 - Collaborating on the development of measures, methods, approaches, and materials to be tested or used.

Program Description - Substantial Program Involvement (Section B.3, pages 11 - 12, continued 2 of 3)

- This award is a cooperative agreement.
- Cooperative agreements are a form of assistance that allows for substantial involvement between ORI and the recipient during the project period.
- ORI substantial programmatic involvement may include:
 - Identification of other organizations/groups/institutions with whom the awardee may be asked to develop cooperative and collaborative relationships and partnerships.
 - Consulting with and assisting the awardee throughout the preparation and dissemination of any information, materials, or products produced under the auspices of the award.
 - Reviewing all communications or disseminated work-product co-branded with HHS, OASH, ORI, or any other HHS component, for prior approval of the communication method and its contents.

Program Description - Substantial Program Involvement (Section B.3, pages 11 - 12, continued 3 of 3)

- This award is a cooperative agreement.
- Cooperative agreements are a form of assistance that allows for substantial involvement between ORI and the recipient during the project period.
- ORI substantial programmatic involvement may include:
 - Assisting the awardee to monitor the progress of the project, which includes but is not limited to collecting, reporting, and analyzing data or information and required comprehensive reporting during the two-year period of performance.
 - Providing prior approval for change of time that Key Personnel are dedicated to the project and for replacement of Key Personnel.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
- 2) Project Description
- 3) Outcomes
- 4) Evaluation
- 5) Dissemination
- 6) Project Management
- 7) Environment and Organizational Capability

Project Narrative Content - Statement of Problem (Section F.3.a.1, page 18)

- Describe the scope and breadth of the problem or critical barrier to progress in the field and potential effects on affected groups or populations (e.g., junior researchers, research administrators, Research Integrity Officers).
- Detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
- 2) Project Description
- 3) Outcomes
- 4) Evaluation
- 5) Dissemination
- 6) Project Management
- 7) Environment and Organizational Capability

Project Narrative Content - Project Description (Section F.3.a.2, pages 18 - 20)

- Describe the nature of the activities to be undertaken, how they address the needs identified in the program announcement, and a clear connection to how they will assist in achieving the overall project goals.
- Describe the overall strategy, methodology, and/or analyses to be used to accomplish the specific aims of the project. Include why the overall approach as described is appropriate. Include how the data will be collected, analyzed, and interpreted.

Project Narrative Content - Project Description (Section F.3.a.2, pages 18 - 20, continued 2 of 5)

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved (e.g., solve a specific problem, develop a new resource).
- List succinctly the specific, measurable, and time-framed objectives of the proposed project as they relate to the project goals.

Project Narrative Content - Project Description (Section F.3.a.2, pages 18 - 20, continued 3 of 5)

- Provide detailed descriptions of specific products or outcomes proposed for development or modification.
- Describe how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and disseminate information and products.

Project Narrative Content - Project Description (Section F.3.a.2, pages 18 - 20, continued 4 of 5)

- Describe the role and makeup of potential subrecipients intended to be involved in completing specific tasks and identify the level of effort each subrecipient is anticipated to provide in completing programmatic activities.
- Note any major barriers you anticipate encountering and how your project will be able to overcome those barriers.

Project Narrative Content - Project Description (Section F.3.a.2, pages 18 - 20, continued 5 of 5)

- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the goals.
- If the project is in the early stages of development, describe any strategies that will be used to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- If applicable, describe and justify the proposed involvement of human subjects (45 C.F.R. Part 46) in the work proposed.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
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Project Narrative Content - Outcomes (Section F.3.a.3, pages 20 - 21)

- Specify the measurable outcome(s) that will result from your project. HHS/OASH will not fund any project that does not include measurable outcomes. A “measurable outcome” is an observable end-result that describes how an activity, event, resource, or approach benefits the intended audience. It demonstrates the “impact” of the activity, event, resource, or approach.
- In addition to discussion in the narrative, describe how you envision the project will benefit the field at large.

Project Narrative Content - Outcomes (Section F.3.a.3, pages 20 - 21, continued)

- Describe how you will report on the outcomes of the project.
- Keep the focus of this section on describing what outcome(s) will be produced by the project. You should use the Evaluation section noted below to describe how the outcome(s) will be measured and reported. Your application will be scored on the clarity and nature of your proposed outcomes, not on the number of outcomes cited. In many cases, it is very appropriate for a project to have only ONE outcome that it is trying to achieve through the intervention reflected in the project's design.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
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Project Narrative Content - Evaluation (Section F.3.a.4, page 21)

- Describe the methods you will use to evaluate the impact of activities you propose.
- Describe the quantitative and/or qualitative tools and techniques that you will employ to measure the outcome(s) and how you will identify and document the “lessons learned.”

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
- 2) Project Description
- 3) Outcomes
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Project Narrative Content - Dissemination (Section F.3.a.5, page 21)

- Describe a comprehensive dissemination plan to communicate key findings to stakeholders, the general public, and other parties who might be interested in the results of the proposed project. HHS/OASH expects that nationwide dissemination of products and knowledge will occur.

Project Narrative Content - Dissemination (Section F.3.a.5, page 21, continued)

- Describe the method you will use to disseminate the project's results and findings in a timely manner and in easily understandable formats to the PHS-funded research community, the general public, and other parties who might be interested in using the results of the project. HHS/OASH may publish (including on a website), all appropriate findings and products. Therefore, you should propose other, innovative approaches to informing parties who might be interested in using the results of your project to inform practice, service delivery, program development, and/or policy-making.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
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Project Narrative Content - Project Management (Section F.3.a.6, page 22)

- Identify the PI, collaborators, and other researchers, including subrecipients, proposed for the project. Include a clear delineation of the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's goals and outcomes.
- Identify the individual who will serve as the Principal Investigator/Project Director and that individual's qualifications. HHS/OASH expects that, throughout the award period, the Principal Investigator/Project Director will have involvement in, and substantial knowledge about, all aspects of the project.

Project Narrative Content - Project Management (Section F.3.a.6, page 22, continued)

- Specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and HHS/OASH.
- Describe the approach that will be used to monitor and track progress on the project's tasks and objectives.

Project Narrative Content (Section F.3.a, pages 17 - 23)

- 1) Statement of Problem
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Project Narrative Content - Environment and Organizational Capability (Section F.3.a.7, pages 22 - 23)

- Describe your organization's capability to successfully implement the proposed project.
- Describe the research/scientific environment in which the work will be done and how it will contribute to the probability of success. This should include a description of the institutional support, equipment, and other physical resources available to the investigators.

Project Narrative Content - Environment and Organizational Capability (Section F.3.a.7, pages 22 - 23, continued 2 of 5)

- Describe how your organization (or the particular division of a larger organization which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses.
- Describe the organizational investment in the success of the investigator and proposed project. Examples of such investment include provision of resources such as office space sufficient for project needs, logistical support such as administrative management and oversight, and financial support such as protected time for research with salary support.

Project Narrative Content - Environment and Organizational Capability (Section F.3.a.7, pages 22 - 23, continued 3 of 5)

- Describe the activities the organization undertakes to “[f]oster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct” (42 C.F.R. § 93.300(c)).

Project Narrative Content - Environment and Organizational Capability (Section F.3.a.7, pages 22 - 23, continued 4 of 5)

- Describe the capabilities of the applicant organization not included elsewhere in the program narrative, such as any current or previous relevant experience and/or the record of the project team in preparing cogent and useful reports, publications, and other products. If appropriate, include an organization chart in your Appendices showing the relationship of the project to the current organization.

Project Narrative Content - Environment and Organizational Capability (Section F.3.a.7, pages 22 - 23, continued 5 of 5)

- Include information about any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals. Applicants may forge collaborations. Collaborations should be described in the application and in accompanying letters of commitment.

Application Appendices (Section F.3.c, pages 32 - 34)

- 1) Work Plan
- 2) Letters of Commitment from Subrecipient Organizations, Consultants, and Agencies
- 3) Curricula Vitae/Résumés/Biographical Sketches for Key Project Personnel
- 4) Proof of Institutional Review Board (IRB) Authorization Agreement (if applicable)
- 5) Bibliography of References Cited in Project Narrative

Considerations, Options, and Resources for Data Management in PHS Funded Research Opportunity No: IR-ORI-21-001

Competitive Application Deadline

Due Date: WEDNESDAY, June 30, 2021

Cutoff Time: 6:00 p.m. ET



Submission Dates and Times (Section A)

Application is due by 6:00 p.m. Eastern Time, Wednesday, June 30, 2021.

- 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.

Eligible Applicants (NOFO, Section E.1, page 14)

Applicant eligibility for this NOFO is:

- Any public or private entity, including faith-based, community-based, and Indian Tribes or Tribal organizations, are eligible to apply.
- Foreign institutions (non-domestic U.S.) entities and foreign components of U.S. organizations are eligible to apply.

Cost Sharing or Matching (Section E.2, page 14)

- **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 Responsiveness Criteria (Section E.3, Pages 14 - 15)

- We will review your application to determine whether it meets the responsiveness criterion in Section E.3.
- 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.
- The responsiveness criteria are as follows:
 - **There are no additional responsiveness criteria for this opportunity.**

Notice of Funding Opportunity (NOFO) Announcement

- The Notice of Funding Opportunity (NOFO) provides information and guidance related to applications.
- Read the entire funding announcement.
- Follow the NOFO carefully!
- **The information provided in the NOFO takes precedence over any conflicting information in other documents.**

Address to Request Application Package (Section F.1, Page 16)

- Obtain an application package electronically by accessing Grants.gov at <http://www.grants.gov/>. Find it by searching the Assistance Listing (formerly CFDA) Number found on page 2 of the NOFO.
- The Assistance Listing (CFDA) Number is 93.137.
- **Be sure to subscribe to the announcement in Grants.gov so you receive notification of any updates to the NOFO or supporting documents.**

Application Submission

- OASH requires that all applications be submitted electronically via Grants.gov unless an exemption has been granted by the grants management officer (Section F.5).
 - **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 www.Grants.gov .
- 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 (Section A.1).
- Contact Grants.gov with any questions or concerns regarding the electronic application process 1-800-518-4726.

Application Submission

Applications must be submitted as three (3) files:

File 1: The ENTIRE project narrative (Section F.3.a)

File 2: The ENTIRE budget narrative, including supporting documentation described in the Budget Narrative content section (Section F.3.b)

File 3: All documents in the appendices uploaded in the Attachments section of your Grants.gov application (Section F.3.c)

Note: required standard forms do not apply toward your page count limitations in the submission requirements as stated in Disqualification Criteria (Section E.4).

Application Submission (Section F.8.a)

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 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 limit.**

Application Submission

- 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.

Application Submission

- To ensure successful submission of your application, carefully follow the step-by-step instructions provided at
<http://www.grants.gov/web/grants/applicants/apply-for-grants.html>
- 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)**
- Assurances for Non-construction Programs (SF-424B)**
- 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) (Section F.4)

- If you are registering a new 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 **must** 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 DUNS number at the time you, the recipient, make a sub-award.**

Funding Restrictions (Section F.7, pages 36 - 38)

- 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. (Section F.3.b.1.o)**
 - **Pre-award costs are not allowed. (Section F.7.a)**
 - **Current Salary Limitation: \$199,300 effective January 2021 (Section F.7.b)**

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 (Section F.3.b.2, page 23)**

Forms, narrative and detailed justification do not count toward page limit.

Application Disqualification (Section E.3)

If your 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 your 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 (Section D).**
- **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 (section E.3).**

Application Responsiveness Criterion (Section E.3)

There are no additional responsiveness criteria for this opportunity.

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 scoring under the evaluation criteria.**
- **Be sure to follow submission instructions carefully.**

Application Review Criteria (Section G.1, pages 40 - 44)

Weighted criteria

- **Statement of Problem (10 points)**
- **Project Description (30 points)**
- **Outcomes and Evaluation (15 points)**
- **Dissemination (15 points)**
- **Project Management (15 points)**
- **Environment and Organizational Capability (15 points)**

Application Merit Review

- Eligible applications will be reviewed and scored by a panel of independent reviewers with technical expertise in applicable fields according to the criteria listed in the NOFO.
- Objective Review Committee 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 (Section G.4, page 46)

- 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.
- **All award decisions, including level of funding if an award is made, are final and you may not appeal.**

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.**

Plan for Oversight of Federal Award Funds (Section F.3.b.2)

- If your internal controls are available online, you may provide the link as part of your plan in the budget narrative.
- We have also included Appendix A, which contains questions applicants may find useful in considering their Plan for Oversight of Federal Funds.

Risk Review Resulting in Non-funded Determination

- If we determine your organization does not meet either or both of the 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 FAPIIS, if certain conditions apply.
- The standards include at a minimum, if you are a prior Federal award recipient the information in FAPIIS 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 FAPIIS 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.

Summary and Tips

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 score.
 - ❑ **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.

Summary and Tips

Project Narrative Description:

- Make the goals and objectives “SMART;” Specific; Measurable; Achievable; Realistic; and Time-framed.
- 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.

Summary and Tips

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.

Summary and Tips

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.

Summary and Tips

Overall:

- Include full names (First Middle Last) for Authorized Official, Principal Investigator/Project Director and all Essential Personnel
- Electronic submission **IS** 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

Program Questions

Program Office Attn:

CAPT Stephen Gonsalves, PhD, MPH

Email: Stephen.Gonsalves@hhs.gov

Telephone: 240-453-8400

Administrative or Financial Questions

Grants Management Specialist:

Jessica Shields

Email: Jessica.Shields@hhs.gov

Telephone: 240-453-8822

Electronic Submission Requirements

Grants.gov Applicant Support

www.grants.gov

Email: support@grants.gov

Telephone: 800-518-4726

Please do not contact OASH Program or Grants office staff for Grants.gov issues.

Question and Answer Session

FAQs will be posted to [Grants.gov](https://www.Grants.gov)



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These slides and a link to the recording of this presentation will be posted on [grants.gov](https://www.grants.gov) following the presentation.
