Office of Research Integrity

Notice of Funding Opportunity: Ensuring Research Integrity - Research, Development, and Demonstration

Opportunity Number: IR-ORI-22-001

Application Due Date:

March 15, 2022 at 6:00 PM Eastern

OVERVIEW

EXECUTIVE SUMMARY

The Office of Research Integrity (ORI) announces the anticipated availability of funds for Fiscal Year (FY) 2022 grant awards under the authority of Section 301 of the Public Health Service Act (42 U.S.C. § 241), as delegated to the Director of ORI.

This notice solicits applications for projects that will: 1) conduct research, on one of the four focus areas identified below, related to ensuring research integrity and compliance with 42 C.F.R. Part 93; 2) develop innovative approaches/tools/resources based on the results of this research; and 3) demonstrate the impact and/or effectiveness of these approaches/tools/resources.

The purpose of this initiative is to ensure the integrity and reliability of PHS-funded research through the development and implementation of innovative practical approaches/tools/resources that improve practices related to one of the following four focus areas: 1) transparency in the conduct or reporting of research; 2) effective communication between authors and/or collaborators for the purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g., conflicts

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of interest, research integrity, rigor, reproducibility, transparency, reliability); 3) handling allegations of research misconduct under 42 C.F.R. Part 93; or 4) interventions to address issues related to research culture and climate (e.g., overly-competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research. We anticipate three to six awards of between $75,000 and $150,000 in total costs (direct plus indirect) per year, for a project period not to exceed two years (two 12-month budget periods).

HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that its application complies with all requirements and instructions.

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FUNDING OPPORTUNITY DETAILS

A. DATES

1. Application Deadline

Your application is due March 15, 2022 by 6 p.m. Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and time. If you do not submit your application by the specified deadline, we will return it to you unread.

You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, Grants and Acquisitions Management (GAM) Division, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS). To obtain an exemption, you must request one via email from GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline.

If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's DUNS number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (e.g., GRANT####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to OASH_Grants@hhs.gov.

Failure to have an active System for Account Management (SAM) registration prior to the application due date will <u>not</u> be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will <u>not</u> be grounds for receiving an exemption to the electronic submission requirement.

GAM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section F.8 ("Other Submission Requirements") for information on application submission mechanisms.

To ensure adequate time to submit your application successfully, OASH recommends that you register as early as possible in Grants.gov because the registration process can take up to one month. You must register an authorizing official for your organization. OASH does not determine your organization's authorizing official; your organization makes that designation.   For

information on registering for Grants.gov, refer to https://grants.gov or contact the Grants.gov Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

2. Technical Assistance

We will provide a technical assistance webinar for potential applicants on January 18, 2022 at 12:00 PM Eastern. Login details will be posted at https://ori.hhs.gov/.

We recommend you review the entire announcement promptly so you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this announcement in Grants.gov so you receive any amendments, question and answer documents, or other updates.

B. PROGRAM DESCRIPTION

The Office of the Assistant Secretary for Health (OASH), Office of Research Integrity announces the anticipated availability of funds for Fiscal Year (FY) 2022 under the authority of Section 301 of the Public Health Service Act (42 U.S.C. § 241), as delegated to the Director of ORI.

Research institutions receiving funding for research from any of the Public Health Service funding components [1] are required 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). Core to ORI's mission is the support of education and outreach activities that aid PHS-funded research institutions in their efforts "to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and…to respond effectively to allegations of research misconduct" (65 F.R. 30600, 30601).

Our Ensuring Research Integrity - Research, Development, and Demonstration Grant Program contributes to this mission by supporting projects that undertake research, development,

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[1] PHS funding components are "any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS." 42 C.F.R. § 93.209. This includes the: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Office of the Assistant Secretary for Health (OASH), and Office of the Assistant Secretary for Preparedness and Response (ASPR).

and demonstration activities to advance the evolving field of research integrity as well as to develop innovative practical approaches, tools, and/or resources, and produce tangible outcomes related to ensuring research integrity and compliance with 42 C.F.R. Part 93.

1. Background

The purpose of this initiative is to ensure the integrity and reliability of PHS-funded research through the development and implementation of innovative practical approaches, tools, and/or resources that improve practices in a focus area(s) related to research integrity and compliance with 42 C.F.R Part 93. We have selected the following four focus areas for Fiscal Year 2022: 1) transparency in the conduct or reporting of research; 2) effective communication between authors/collaborators for the purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g., conflicts of interest, research integrity, rigor, reproducibility, transparency, reliability); 3) handling allegations of research misconduct under 42 C.F.R. Part 93; or 4) interventions to address issues related to research culture and climate (e.g., overly-competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research.

This notice solicits applications for projects that will: 1) conduct research, on one of the four focus areas identified above, related to ensuring research integrity and compliance with 42 C.F.R. Part 93; 2) develop innovative approaches/tools/resources based on the results of this research; and 3) demonstrate the impact and/or effectiveness of these approaches/tools/resources.

The proposed project should contain feasible ideas with tangible/measurable outcomes supported by an appropriate budget request and work plan to meet the project goals. The proposed project period must not to exceed two years (i.e., two 12-month budget periods). You may propose a shorter project period of one year if the project goals and outcomes are achievable. Recipients will be required to submit a non-competing continuation application for a second budget period for any project period exceeding 12 months. Funding for the second budget period will be contingent upon availability of funding, satisfactory performance (including recipient progress towards meeting stated project milestones and goals, timely submission of required reports, and compliance with all grant terms and conditions), and the best interests of the government. This funding opportunity does not support projects with the primary purpose of holding meetings, conferences, or workshops. See opportunity number IR-ORI-22-002 for those purposes.

We encourage proposed projects to include collaboration or consultation with individuals and/or organizations with experience in handling issues or providing guidance related to research integrity, research climate/culture, the responsible conduct or research, and/or compliance with 42 C.F.R Part 93. This may include, but is not limited to, institutional research integrity officers; professional organizations; others who have direct experience with 42 C.F.R. part 93; institutional attorneys experienced with these matters. We also encourage proposed projects to include

individuals actively engaged in, or training for, careers in research, and whenever practical, take place in research settings.

2. Expectations

We expect the recipient to:

a. Conduct research related to ensuring research integrity

We expect that you will conduct research for the purpose of informing the development and implementation of innovative practical approaches, tools, and/or resources that improve practices in one or more of the FY 2022 focus areas related to ensuring research integrity and compliance with 42 C.F.R. Part 93.

We expect that research activities and all other activities of the proposed project will concentrate on at least one of the four FY 2022 focus areas:

1) Transparency in the conduct or reporting of research;

2) Effective communication between authors/collaborators for the purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g. conflicts of interest, research integrity, rigor, reproducibility, transparency, reliability);

3) Handling allegations of research misconduct under 42 C.F.R. Part 93;

4) Interventions to address issues related to research culture and climate (e.g., overly-competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research. Interventions may include activities that promote a positive culture/climate or inhibit the perpetuation of a negative climate/culture.

b. Develop innovative and practical approaches, tools, and/or resources

We expect that you will develop, based on the results of the research described above, innovative and practical approaches, tools, and/or resources (collectively, "materials") that will contribute to researchers' and institutions' efforts to ensure the integrity and reliability of PHS-funded research and/or compliance with 42 C.F.R. Part 93. You should design and develop these materials such that they can be readily adapted for a specific research setting and/or discipline, if necessary, but otherwise directly used or implemented to facilitate improved practices at the level of the relevant stakeholder (i.e., individual researcher/research group, research administrator, or research institution). Additionally, you should design all materials with ease of use and implementation for the end user in mind.

c.   Demonstrate the impact and/or effectiveness of the materials developed

We expect you to implement and evaluate the materials developed above to determine the ease with which they can be directly used by the relevant stakeholder(s) (i.e., individual researcher/research group, research administrator, or research institution), their effectiveness in facilitating improved practices, and their impact on research integrity and/or compliance with 42 C.F.R. Part 93. We expect that you will revise the materials as necessary to address issues, identified during the evaluation process, that may prevent effective implementation by the relevant stakeholders.

d.   Disseminate the materials developed under the auspices of this grant

The purpose of this funding opportunity is to develop innovative practical materials that researchers, research administrators, and/or research institutions can implement to improve practices and ensure the integrity of PHS-funded research and/or compliance with 42 C.F.R. Part 93. For this reason, we expect that, as relevant, you will make researchers, research administrators, and research institutions aware of the availability of and provide free access to the materials developed above.

We expect that you will develop and implement a comprehensive, time-framed dissemination plan to communicate key findings to stakeholders, the public, and other parties who might be interested in the results of the proposed project. Your plan should include a description of the method that will be used to disseminate the project's results and findings in a timely manner and in easily understandable formats to the PHS-funded research community, the public, and other parties who might be interested in using the results of the project.

C. AUTHORITY

Section 301, Title III of the Public Health Service Act (42 U.S.C. § 241)

D. FEDERAL AWARD INFORMATION

The Office of Research Integrity intends to make funds available for competing grant awards. The final funding amount will not be determined until enactment of the FY 2022 federal budget.

We will fund awards in annual increments (budget periods) and generally for a period of performance up to 2 years, although we may approve shorter periods of performance. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the Government.

E. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private entity is eligible to apply for an award under this announcement. Faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply. Examples of eligible Organizations include:

- State Governments

- U.S. territories

- County Governments

- City or township governments

- Special district governments

- Independent school districts

- Public and State controlled institutions of higher education

- Native American tribal governments (Federally recognized)

- Public Housing authorities/Indian housing authorities

- Native American tribal organizations (other than federally recognized tribal governments)

- Nonprofits having 501(c)(3) status with the IRS, other than institutions of higher education

- Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

- Private institutions of higher education

- For profit organizations, including small businesses.

- Foreign institutions (non-domestic U.S.) entities and foreign components of U.S. organizations are eligible to apply. Note: to receive an award the proposed activity must provide a domestic benefit, such as promoting research integrity among PHS-funded institutions both within the U.S. and abroad.

2. 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 as described in Section F.3.b.1)(t) Voluntary cost sharing is not expected for research applications. 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 cost sharing or matching, whether required or voluntary, 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. See Section F.3.b.1(s). Any change in the responsibility to provide cost sharing or matching at that level will require prior approval of the grants management officer.

3. Other – Application Responsiveness Criteria

There are no application responsiveness criteria.

4. Application Disqualification Criteria

If you successfully submit an application, we will screen it to ensure it meets the below requirements. If we determine your application fails to meet the criteria described below, we will disqualify it, that is, we will **not** review it and will give it **no** further consideration.

(a)   You must submit your application electronically via https://grants.gov/ (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section (A.1) of this announcement.

(b)   If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.

(c)   HHS/OASH/GAM deems your application eligible according to section E.1 Eligible Applicants.

(d)   You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.

(e)   Your application must be submitted in the English language and must be in the terms of U.S. dollars (45 C.F.R. § 75.111(a)).

(f)   Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ " x 11" inch page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.

(g)   Your Project Narrative must not exceed 30 pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).

(h)   Your total application, including the Project Narrative plus Appendices, must not exceed 75 pages. NOTE: items listed in "(f)" immediately above do not count toward total page limit.

(i)   Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.

(j)   Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.

(k)   If your application includes cost sharing (voluntary or required), you must include in your budget narrative a non-federal sources justification.

F. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at https://www.grants.gov/. You can find it by searching on the CFDA number shown on page 1 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

OASH Grants and Acquisitions Management Division

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a.   Application Format

Your application must be prepared using the forms and information provided in the online application package. This includes but is not limited to: SF-424 Application for Federal Assistance; SF-424A Budget Information for Non-Construction Programs; SF-424B Assurances for Non-Construction Programs.; SF-LLL Disclosure of Lobbying Activities; and Project Abstract Summary.

We encourage individuals to use their full name (first, middle, last) on the Standard Forms and other documents such as resumes and curriculum vitae to distinguish them for verification in the System for Award Management exclusion records. Delays may result in award processing if full names are not provided. NOTE: only one Project Director/Principal Investigator will be named on any resulting award. You should clearly identify the individual in that role in your application.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section E.4. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria.

Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices when printed on 8.5" X 11" paper GAM, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

You should use an easily readable typeface, such as Times New Roman or Arial. You *must* use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

b.   Appendices Format

Your Appendices should include any specific documents outlined in Section F.3.c, under the heading "Appendices" in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

c.   Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

Research awards may enter zero for "Estimated number of people to be served as a result of the award of this grant."

d.   Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

3. **Application Content**

Successful applications will contain the following information:

a.   Project Narrative Content

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following components:

1) Project Description

You should:

- Describe the proposed project and how it will address the Expectations identified in Section B.2 of this announcement. You should:
  - Explain the rationale for the proposed project.
  - Describe the scope and breadth of the problem and critical barrier(s) to progress on the selected research integrity topic/focus area. Describe potential impacts on affected groups or populations (e.g., researchers, research administrators, Research Integrity Officers).
  - Describe in detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified.

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- State concisely the goals of the proposed project and summarize the expected outcome(s), including the impact that the results of the proposed project will exert on the selected topic/focus area (e.g., solve a specific problem, provision of a new resource).

- Describe the overall strategy, activities (e.g., research, material development, implementation, and evaluation efforts), and methods that you will use to accomplish the goals of the project. Include how the data will be collected, analyzed, and interpreted.

- Describe why the specific activities were selected. Explain how the proposed activities will help to achieve the overall project goals and outcomes. Indicate why the overall approach as described is appropriate. Present a clear connection between selected research integrity topic/focus area and the proposed activities.

- Describe any novel approaches or methods you intend to employ to achieve the project goals. If utilizing approaches or methods that do not diverge substantially from existing practices, describe the novelty in the application of those methods to the topic. Reference, where applicable, existing approaches for the purpose of contrasting the novel approaches or methods you propose.

- List succinctly the specific and time-framed objectives of the proposed project as they relate to the project goals.

- Provide detailed descriptions of specific materials proposed for development or modification.

- List succinctly the anticipated, specific, and measurable outcomes of the proposed project as they relate to the project goals.

- Discuss potential problems, alternative strategies, and benchmarks for success with respect to project goals. Note any major barriers you expect to encounter as well as how your project will be able to overcome those barriers.

- Describe how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and disseminate information and products.

- Describe the role and makeup (e.g., research administrator, research integrity officer, research faculty, professional society, publisher, editor) 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.

- If the project is in the early stages of development, describe any strategies that you will use 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 proposed work by describing the following:

    o Characteristics of the subject population, including their anticipated number, age range, etc.

    o The sampling plan and justification for proposed plan as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.

    o Data that will be collected from human subjects for the project(s) described in the application.

    o Who will have access to individually identifiable private information about human subjects.

    o How the records and/or data will be collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

    o Plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

2) Outcomes

You should:

- 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 you will assess the project outcome(s). 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.

- Specify the tangible/measurable outcome(s) that will result from your project. HHS/OASH will not fund any project that does not include measurable

outcomes. A tangible/measurable outcome is an observable end-result that describes how an activity, event, resource, or approach helps the intended audience; it is large enough to be noticed. It demonstrates the "impact" of the activity, event, resource, or approach. For example, a tangible/measurable outcome may be a change in knowledge, skill, attitude, awareness, or behavior about the subject matter because of the project. This may include new knowledge or a tangible/measurable increase in institutional awareness. A tangible/measurable outcome is not a quantifiable outcome such as the percentage of participants reporting a change in practice or the percent increase of knowledge on a specific topic. A tangible/measurable outcome is not a measurable/quantifiable "output," such as the number of materials produced, the number of stakeholders using these materials, or the number of lectures/training sessions provided. These numbers in combination with other measures may contribute to the overall evaluation of the activity or project.

- In addition to any discussion in the Project Description, describe how you envision the project will benefit the field at large.

- In addition to any discussion in the Dissemination section below, describe how you will report on the outcomes of the project.

3) Evaluation

You should:

- Describe the quantitative and/or qualitative tools and techniques that you will employ to assess and evaluate the ease with which the materials developed as part of this project can be directly used by the relevant stakeholder(s), their effectiveness in facilitating improved practices, and their impact on research integrity and/or compliance with 42 C.F.R. Part 93.

- Describe the quantitative and/or qualitative tools and techniques that you will employ to assess and evaluate outcome(s) and how you will identify and document the "lessons learned."

- Describe how you will collect and report evaluation data. Describe how you will ensure the validity and reliability of these data.

4) Dissemination

You should:

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

- 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 public, and/or other parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policymaking.

5) Project Management

You should:

- Identify the Principal Investigator, collaborators, and other researchers, including subrecipients, proposed for the project. Include a clear delineation of the roles and responsibilities of project staff and subrecipients, their relevant expertise, and how they will contribute to achieving the project 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 be involved in, and have substantial knowledge about, all aspects of the project.

- 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 you will use to monitor and track progress on the project's tasks and objectives.

6) Environment and Organizational Capability

You should:

- Provide a contingency plan for modification of in-person activities in the event of a resurgence of COVID-19 or precautions under other public health emergency conditions.

- 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.

- Describe how your organization (or the 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.

- 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)). Describe the way in which the proposed project will contribute to and enhance the recipient's (institution's) activities related to research integrity and/or compliance with 42 C.F.R. Part 93.

- Describe the capabilities of your 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.

- 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. You may forge collaborations. Describe collaborations in the application and accompanying letters of commitment.

b.   Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF-424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance).

Please be sure to carefully review section F.7 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF-424A for the first year of the proposed project. Provide a budget justification, which includes explanatory text and line-item detail, for the first year of the proposed project. The budget narrative should describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not include costs beyond the first budget period** in the object class budget in box 6 of the SF-424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget period.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. For example, if you are proposing to provide services to clients, you should describe how many clients are you expecting to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (when required) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Sample Budget Table

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	$100,000	$25,000	$125,000

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel. **Subrecipient/contract and consultant activities must be described in sufficient detail to describe accurately the project effort that each will conduct**.

1) Object Class Descriptions and Required Justifications

    (a)   Personnel Description

Costs of staff salaries and wages, excluding benefits.

    (b)   Personnel Justification

Clearly identify the project director or principal investigator, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent: annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see F.7.2). Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. Contractors and consultants should not be placed under this category.

Sample Personnel Table

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Project Director, John K. Doe	50%	$100,000	$50,000	$0	$50,000
Data Assistant, Susan R. Smith	10%	$30,000		$3,000	$3,000

    (c)   Fringe Benefits Description

Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

    (d)   Fringe Benefits Justification:

Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

    (e)   Travel Description

Costs of travel by staff of the applicant organization only.

    (f)   Travel Justification

For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage

allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors.

(g)   Equipment Description

Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or $5,000. (Note: Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non- Federal entity's regular accounting practices.) See 45 C.F.R. § 75.2 for additional information.

(h)   Equipment Justification

For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

(i)   Supplies Description

Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than $5,000.

(j)   Supplies Justification

Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

(k)   Contractual Description

Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc.   Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. This line item is not for individual consultants.

(l)　　Contractual Justification

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 C.F.R. § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134 and currently set at $250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Note: Whenever you intend to delegate part of the project to another entity (including non-employee individuals), you must provide a detailed budget and budget narrative for each subrecipient/contractor, by title/name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency.

(m)　　Other Description

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

(n)　　Other Justification

Provide computations, a narrative description, and a justification for each cost under this category.

(o)　　Indirect Costs Description

Total amount of indirect costs. This category has one of two methods that you may select. You may only select one.

- Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.

- Per 45 C.F.R. § 75.414 (f) Indirect (F&A) costs, "any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, … may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or

inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time."

This method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

(p)   Indirect Costs Justification

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

(q)   Program Income Description

Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 C.F.R. § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 C.F.R. § 75.307 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

(r)   Program Income Justification

Describe and estimate the sources and amounts of program income that this project may generate if funded. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. This amount should be reflected in box 7 of the SF-424A.

(s)   Non-Federal Resources Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the criteria listed in 45 C.F.R. § 75.306.

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For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by period of performance for fully-funded awards, even if the justification by budget period, or by period of performance for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports.

For awards that do not require matching or cost sharing by statute or regulation, where "cost sharing" refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. Note, you will not receive any preference, priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

(t)   Non-federal Resources Justification

You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding ($)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by period of performance for fully-funded awards). **If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review**.

2) Plan for Recipient Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.

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- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.

- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.

- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Grants and Acquisitions Management Division via the Payment Management System as well as timely and appropriate withdrawal of cash from the Payment Management System.

If your internal controls are available online, it is recommended that you provide the link as part of your plan in the budget narrative. We have also included supplementary information in Section K.1, which contains questions applicants may find useful in considering their Recipient Plans for Oversight of Federal Funds.

c. Appendices

All items described in this section will count toward the <u>total</u> page limit of your application. You must submit them as **a single electronic file** uploaded to the Attachments section of your Grants.gov application.

1) Work Plan

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of period of performance. However, each year's activities should be fully attainable in one budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should show the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task.

2) Letters of Commitment from Subrecipient Organizations, Consultants, and Agencies

You should include signed Letters of Commitment for all organizations and entities that have been specifically named as a subrecipient to carry out any aspect of the project. The signed letters of commitment must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of the applicant. The organization's expertise, experience, and access to the targeted population(s) should also be described in the letter of commitment.

Letters of commitment are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together

in the future, but they lack specificity. You should NOT provide letters of support, and letters of support such as this will not be considered during the review.

3) Curricula Vitae/Résumés/Biographical Sketches for Key Project Personnel

You must submit with your application curriculum vitae and/or résumés of the Project Director/Principal Investigator and all other Key Personnel. Key Personnel include those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum the Program Manager/Program Coordinator. We encourage individuals to use their full name (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records. Omission of a middle name or initial may delay the award of an approved application. You should use the formatting common to those documents. (See https://grants.nih.gov/grants/forms/biosketch.htm for templates and sample biographical sketches.)

4) Proof of Institutional Review Board (IRB) Authorization Agreement (if applicable)

Upload documentation received from the IRB with authority over the proposed research that certifies the status (e.g., authorization, exemption, submitted, under review, etc.) of the proposed project. Do not submit your IRB application or ancillary elements of your IRB application, such as consent forms, with your project proposal.

5) Bibliography of References Cited in Program Narrative

Use a citation format of your choice. We do not require a specific citation format but request consistency throughout the application and a clear connection to the source material. Most style guides include format guidance for citations.

4. **Unique Entity Identifier and System for Award Management (SAM)**

You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain.

You will find instructions on the Grants.Gov web site as part of the organization registration process at https://www.grants.gov/web/grants/applicants/organization-registration.html.

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations.

If you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to SAM.GOV. For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/gsafsd_sp?sys_kb_id=8cfe46491b1cb8909ac5ddb6bc4bcbbb&id=kb_article_view&sysparm_rank=1&sysparm_tsqueryId=c6131c131bdcf0d0a7d7da49bc4bcb1a.

A quick start guide for registrants is available at https://www.fsd.gov/sys_attachment.do?sys_id=80f49f211bdcfc909ac5ddb6bc4bcb76. You should allow a minimum of five days to complete an initial SAM registration. Allow up to 10 business days after you submit your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.

If your organization is already registered in SAM, you must renew your SAM registration each year. Organizations registered to apply for Federal awards through http://www.grants.gov will need to renew their registration in SAM.

You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, this information must be included on a Notice of Award. For instructions on updating this information see https://www.fsd.gov/sys_attachment.do?sys_id=d08b64ab1b4434109ac5ddb6bc4bcbbc.

It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.

If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 C.F.R. § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

May determine that 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.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in Section A.1 of this announcement.** Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your 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. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with https://grants.gov. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A "system problem" does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

6. Intergovernmental Review

This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," as implemented by 45 C.F.R. part 100.

7. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 C.F.R. part 75 "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards," Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 C.F.R. § 75.414. See the Budget Narrative section of this announcement for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at https://rates.psc.gov/fms/dca/map1.html.

1) Pre-Award Costs

Pre-award costs (per 45 C.F.R. § 75.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the HHS awarding agency.

Pre-award costs are NOT allowed.

2) Salary Rate Limitation:

Each year's appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2021, the Executive Level II salary is $199,300. This amount reflects an individual's base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's *actual* base full-time salary: $350,000 50% of time devoted to project, i.e., 0.5 FTE	
Direct salary ($350,000 x 0.5)	$175,000
Fringe (25% of salary)	$43,750
Total	$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full-time salary *adjusted* to Executive Level II: $199,300 with 50% of time devoted to the project	
Direct salary ($199,300 x 0.5)	$99,650
Fringe (25% of salary)	$24,913
Total amount allowed	$124,563

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

   a.   Electronic Submission

HHS/OASH requires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at https://grants.gov.

Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. **We do not accept Microsoft Excel files**.

We strongly recommend 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. Please note, although Grants.gov allows you to attach any file format as part of your application, we restrict this practice and only accept the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files. Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed information in the application will not be forwarded for consideration.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a

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single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

b.   Important Grants.gov Information

You may access the electronic application for this program on https://grants.gov. You must search the downloadable application page by the Opportunity Number or Assistance Listing (formerly CFDA) number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should 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. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Section I.3 for contact information.

See Section F.4 for requirements related to DUNS numbers and SAM registration.

c.   Program-Specific Requirements

There are no program specific requirements.

G. APPLICATION REVIEW INFORMATION

1. Criteria

Federal staff and an independent review panel will assess all eligible applications according to the following three equally-weighted criteria: a) project description, b) outcomes, evaluation, and dissemination, and c) project management and environment and organizational capability. Disqualified applications will not be reviewed against these criteria.

a.   Project Description

To what degree does the proposal:

- Explain how the proposed project, including the materials proposed for development and/or modification, will specifically address all of the Expectations identified in Section B.2 of this announcement? Briefly, the applicant is expected to propose and implement a project to:

  o   Conduct research in one or more of the four FY 2022 focus areas (i.e., 1) transparency in the conduct or reporting of research; 2) effective communication between authors/collaborators for the

purpose of avoiding, mitigating, and resolving authorship/collaborator disputes and/or issues related to the integrity of the research (e.g. conflicts of interest, research integrity, rigor, reproducibility, transparency, reliability); 3) handling allegations of research misconduct under 42 C.F.R. Part 93; or 4) interventions to address issues related to research culture and climate (e.g., overly competitive environments, toxic workplaces, bullying, harassment, etc.) that can negatively impact the integrity, conduct, quality, and reliability of research).

- o Develop, based on the results of the research conducted under the auspices of this grant, innovative practical approaches, tools, and/or resources that will contribute to researchers' and institutions' efforts to ensure the integrity and reliability of PHS-funded research and/or compliance with 42 C.F.R. Part 93.

- o Demonstrate the impact and/or effectiveness of the approaches, tools, and/or resources developed under the auspices of this grant.

- o Disseminate, and make freely available for use by the PHS-funded research community, the approaches, tools, and/or resources developed under the auspices of this grant.

- Explain the rationale for the proposed project; describing how the overall strategy, activities (e.g., research, material development, implementation, and evaluation efforts), and methodology (including how the data will be collected, analyzed, and interpreted) are appropriate and will assist in achieving the overall project goals and outcomes?

- Describe the scope and breadth of the problem and critical barrier(s) to progress on the selected research integrity topic/focus area?

- Detail how the project will affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified (e.g., researchers, research administrators, Research Integrity Officers)?

- Describe how novel approaches or methods, or applications of existing practices, are employed to achieve project goals?

- Discuss how potential problems, alternative strategies, and benchmarks for success will be approached to ensure project goals are achieved?

b. Outcomes, Evaluation, and Dissemination

To what degree does the proposal:

- Specify the tangible/measurable outcome(s) that will result from the project, as described in the Project Narrative, and clearly correlate these outcomes with project goals?

- Describe how the project, in addressing the Expectations identified in the Program Description section of this announcement, will benefit the field at large?

- Describe the quantitative and qualitative tools and techniques that the applicant will employ to assess and evaluate the ease with which the materials developed as part of this project can be directly used by the relevant stakeholder(s), their effectiveness in facilitating improved practices, and their impact on research integrity and/or compliance with 42 C.F.R. Part 93?

- Describe the quantitative and qualitative tools and techniques that the applicant will employ to assess and evaluate the outcome(s), how the applicant will identify and document the "lessons learned," and how the applicant will ensure that the evaluation data that are collected are reliable and valid?

- Describe the method that will be used to disseminate the project's results and findings in a timely manner and in easily understandable formats to the target audience, the general public, and/or other parties who might be interested in using the results of the project?

- Present a comprehensive dissemination plan that effectively communicates key findings to stakeholders, the public, and other parties who might be interested in the results of the proposed project? Does the plan address how HHS/OASH expectations, regarding nationwide dissemination of products and knowledge, will be met?

c. Project Management and Environment and Organizational Capability

To what degree does the proposal:

- Provide a clear delineation of the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's objectives and outcomes? 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 an effective approach to check and track progress on the project's tasks and objectives and ensure that the project's goals are achieved?

- Describe an effective plan for mitigating impacts due to precautions implemented in response to COVID-19 or other public health emergency conditions?

- Identify the individual who will serve as the Principal Investigator/Project Director; describe that individual's relevant qualifications; and indicate how, throughout the award period, the Principal Investigator/Project Director will maintain involvement in, and substantial knowledge about, all aspects of the project?

- Describe a research/scientific environment, in which the work will be done, that will contribute to the probability of meeting project goals? In this environment, are institutional support, equipment, and other physical resources sufficiently available to the investigators?

- Describe an organizational investment in the success of the investigator and proposed project (e.g., 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)?

2. Review and Selection Process

Each OASH Program office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and rate the applications, focusing their comments and rating decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Director, Office of Research Integrity will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. No award decision is final until a Notice of Award is issued by the Grants Management Officer.

3. Review of Risk Posed by Applicant

GAM will evaluate, in accordance with 45 C.F.R. § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a reimbursable rather than cash advance basis. We will use a risk-based approach and may consider any items such as the following:

a.   Your financial stability;

b.   Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;

c.   History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

d.   Reports and findings from audits performed; and

e.   Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently $250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 C.F.R. § 75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must "demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative

agreements, or procurement awards; and integrity and business ethics." 45 C.F.R. § 75.205(a)(2); see also 45 C.F.R. §75.212 for additional information.

4. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued. All award decisions, including the level of funding if an award is made, are final and you may not appeal.

OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B "Federal Award Information," as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later period of performance start date.

H. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

We do not release information about individual applications during the review process. If you would like to track your application, please see instructions at https://www.grants.gov/web/grants/applicants/track-my-application.html. The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH GAM. If you are successful, you will receive this document via a system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization's information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 C.F.R. 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.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf. Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 C.F.R. parts 74 and 92 have been superseded by 45 C.F.R. part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 C.F.R. § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

3. Program Specific Terms and Conditions

There are no program specific terms and conditions.

4. Closeout of Award

Upon expiration of your period of performance, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the Principal Investigator/ Project Director, we must complete a unilateral closeout with the information available to us. (See H.16 Reporting below for closeout reporting requirements.) If you do not

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submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). As a result, we may also determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

5. Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

6. Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and 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/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your 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 your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, 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 guidance on administering your program 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.

Contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf, provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. For further guidance on providing culturally and linguistically appropriate services, you should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

7. **Smoke- and Tobacco-free Workplace**

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the

HHS/OASH mission to protect and advance the physical and mental health of the American people.

8. Acknowledgement of Funding

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

> This [project/publication/program/website, etc.] was supported by [Award Number] issued by the Office of the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $XX with 100 percent funded by [PROGRAM OFFICE]/OASH/HHS.

Recipients must also include a disclaimer stating the following

> The contents are solely the responsibility of the author(s) and do not necessarily represent the official views of, nor an endorsement by, [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

9. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 C.F.R. § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 C.F.R. § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104) (See https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm).

11. Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/.

12. Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 C.F.R. § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

13. Prohibition on certain telecommunications and video surveillance services or equipment.

As described in 2 C.F.R. 200.216, recipients and subrecipients are prohibited from obligating or spending grant funds (to include direct and indirect expenditures as well as cost share and program) to:

a.   Procure or obtain;

b.   Extend or renew a contract to procure or obtain; or

c.   Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

> 1) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera

Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

2) Telecommunications or video surveillance services provided by such entities or using such equipment.

3) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

14. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. You may find it online at https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Applicants that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to https://www.hhs.gov/about-research-participation.

OASH may require, as part of any award, the submission of all IRB approvals within 5 days of the IRB granting the approval and before any work requiring IRB approval begins.

15. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at https://ori.hhs.gov/assurance-program.

16. Reporting

a. Performance Reports

You must submit performance reports on a **semiannual** basis. Your performance reports must address content required by 45 C.F.R. § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov).

You will also be required to submit a final performance report covering the entire period of performance 120 days after the end of the period of performance. You must submit the final report by upload to our grants management system (GrantSolutions.gov).

b. Performance Measures

At the end of each reporting period, you should be able to:

- Demonstrate progress toward stated goals set forth in the Project Narrative and Work Plan, acknowledging barriers to progress and approaches to overcoming them;

- Describe how the project met milestones identified in the proposal; and

- Describe any approaches, tools, and/or resources, developed and disseminated.

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire period of performance 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (https://pms.psc.gov). Quarterly cash reporting via PMS on the FFR is also required.

Once submitted and accepted, your financial reports will be available in GrantSolutions, which is our grant management system.

d. Audits

If your organization receives $750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 45 C.F.R. 75, subpart F.

e. Non-competing Continuation Applications and Awards

Each year of the approved period of performance, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. OASH will award continuation

funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. Additionally, failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

f.   FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (https://www.FSRS.gov) for all sub-awards and sub-contracts issued for $25,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

g.   Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 C.F.R. part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 C.F.R. part 75.

h.   Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 C.F.R. § 180.335, you as the participant must notify OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;

- Have been convicted within the preceding three years of any of the offenses listed in 2 C.F.R. § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;

- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 C.F.R. § 180.800(a); or

- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 C.F.R. § 180.350, you must give immediate written notice to OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 C.F.R. § 180.335; or

- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 C.F.R. § 180.335.

I. CONTACTS

1. Administrative and Budgetary Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Duane Barlow

Grants and Acquisitions Management

1101 Wootton Parkway, Plaza Level

Rockville, MD 20852

Phone: 240-453-8822

Email: Duane.Barlow@hhs.gov

2. Program Requirements

For information on program requirements, please contact the program office representative listed below.

CAPT Stephen Gonsalves, PhD, MPH, BC-FNP

Office of Research Integrity

1101 Wootton Parkway, Suite 240

Rockville, MD 20852

Phone: 240-453-8400

Email: Stephen.Gonsalves@hhs.gov

3. Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support

Website: https://www.grants.gov

Phone: 1-800-518-4726

Email: support@grants.gov

J. OTHER INFORMATION

1. Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for periods shorter than indicated. 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.

2. Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

- 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

- Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.

- Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.

- Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application**.

  - Work Plan

  - Letters of Commitment from Subrecipient Organizations, Consultants, and Agencies

  - Curricula Vitae/Résumés/Biographical Sketches for Key Project Personnel

- o Proof of Institutional Review Board (IRB) Authorization Agreement (if applicable)

- o Bibliography of References Cited in Program Narrative

Wanda K. Jones, DrPH, MT(ASCP)

Digitally signed by Wanda K. Jones, DrPH, MT(ASCP)
Date: 2021.12.22 09:37:49 -05'00'

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Wanda K. Jones, DrPH, MT(ASCP)   Date

Acting Director, Office of Research Integrity

K. SUPPLEMENTARY MATERIALS

1. Considerations in Recipient Plans for Oversight of Federal Funds

(See also Section F.3.b.2)

To the maximum extent possible, a recipient organization should segregate responsibilities for receipt and custody of cash and other assets; maintaining accounting records on the assets; and authorizing transactions. In the case of payroll activities, the organization, where possible, should segregate the timekeeping, payroll preparation, payroll approval, and payment functions.

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?

- Are specific officials designated to approve payrolls and other major transactions

- Does the time and accounting system track effort by cost objective?

- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?

- Do the procedures for cash receipts and disbursements include:

    o Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?

    o Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?

    o All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?

    o Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?