DEPARTMENT OF HEALTH AND HUMAN SERVICES

AGENCY: Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI)

FUNDING OPPORTUNITY TITLE: Announcement of the Anticipated Availability of Funds for Phase I Research on Research Integrity

ACTION: Notice

ANNOUNCEMENT TYPE: INITIAL COMPETITIVE GRANT

FUNDING OPPORTUNITY NUMBER: IR-ORI-15-001 – Amendment 2

CFDA NUMBER: [93.085]

CFDA PROGRAM: Research of the Responsible Conduct of Research (RCR)

Applications are due by April 20, 2015 by 5 p.m. EST. To receive consideration, applications must be received electronically via Grants.gov by the HHS Office of the Assistant Secretary for Health (HHS/OASH), Office of Grants Management (OGM) no later than this due date. Applications which do not meet the specified deadlines will be returned to the applicant unread. All applicants must submit electronically via Grants.gov unless they obtain a written exemption from this requirement 2 business days in advance of the deadline by the Director, HHS/OASH Office of Grants Management. To obtain an exemption, applicants must request one via e-mail from the HHS/OASH Office of Grants Management, and provide details as to why they are technologically unable to submit electronically through Grants.gov portal. Requests should be submitted at least 4 business days prior to the application deadline to ensure the request can be considered prior to 2 business days in advance of the deadline. If requesting an exemption, include the following in the e-mail request: the HHS/OASH announcement number; the organization's DUNS number; the name, address and telephone number of the organization; the

name and telephone number of the Authorizing Official; the Grants.gov Tracking Number (GRANTXXXX) assigned to the submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to ogm.oash@hhs.gov. Note: failure to have an active System for Account Management (SAM) registration will not be grounds for receiving an exemption to the electronic submission requirement.

The HHS/OASH Office of Grants Management will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via e-mail) from applicants obtaining prior written approval. The application must still be submitted 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 e-mail) with an approved written exemption will be accepted. *See* the heading "**APPLICATION and SUBMISSION INFORMATION**" for information on application submission mechanisms.

To ensure adequate time to successfully submit the application, HHS/OASH recommends that applicants register as early as possible in Grants.gov since the registration process can take up to one month. For information on registering for Grants.gov, refer to http://www.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.

Applicants are strongly encouraged to register multiple authorized organization representatives.

Technical Assistance: Technical assistance will be provided by Ann Hohmann by phone (240-453-8431) Monday through Thursday between 10 am and 3 pm EST or by e-mail (Ann.Hohmann@hhs.gov) starting January 12, 2015.

EXECUTIVE SUMMARY: The Office of Research Integrity (ORI) announces the anticipated availability of funds for Fiscal Year (FY) 2015 grant awards under the authority of Sec. 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 to conduct innovative research related to the prevention of research misconduct, protection of whistleblowers, and the furtherance of research integrity in this country and internationally.

The Research on Research Integrity Program is structured in two phases:

> Phase I: The objective for Phase I is to establish project merit and feasibility and to generate preliminary data prior to seeking further support for Phase II. Up to twelve Phase I awards are anticipated with a direct cost ceiling of $75,000; indirect costs will be additional. The anticipated period of performance is from 09/01/2015 through 08/31/2016.
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> Phase II: Phase II constitutes a separate competition limited to successful Phase I awardees. The objective for Phase II is to build upon results achieved in Phase I. Funding is based on success demonstrated in Phase I, the merit and feasibility of the Phase II proposal, and the availability of funds. ORI anticipates that Phase II awards will have a ceiling of $125,000 per year for a two-year project period. The anticipated period of performance is from 09/01/2016 through 08/31/2018. OASH/ORI anticipates accepting Phase II applications in Spring 2016 subject to the availability of funds.

I. FUNDING OPPORTUNITY DESCRIPTION

Purpose

The purpose of this Funding Opportunity Announcement (FOA) is to foster innovative approaches to empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research. Integrity is defined as the use of honest and verifiable methods in proposing, performing, and evaluating research and reporting research results with particular attention to adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms.

Background

ORI research on research misconduct and research integrity has been funded over the years with the goal of providing the evidence base for ORI to create or modify educational programs to encourage the responsible conduct of research (RCR). As a result of a review of that research and research priorities, ORI is issuing this announcement to change the direction of ORI-funded research, from a descriptive and educational focus to one that is designed explicitly to address the following: (a) identify risk factors that make misconduct more likely; (b) create an evidence base for proactive interventions; and, (c) build on lessons learned through previous research and the experiences of those who have been involved in guiding research misconduct proceedings. The core assumption of this announcement is that the social, cultural, and behavioral mechanisms underlying research misconduct must be understood to address the problem.

The research will be reviewed and funded in a two-phase process. For the first phase, ORI is seeking small-scale, developmental research projects that have the following characteristics:

- The research is discipline-specific or cross-disciplinary and arises out of the theoretical and empirical literature of social science disciplines seeking to understand behavior in a social context: anthropology, economics, sociology, criminology (specifically white collar crime), and psychology (particularly social and cognitive).
- The project includes collaboration with institutional research misconduct officials and/or others who have direct experience with 42 C.F.R. Part 93, including institutional attorneys experienced with institutional research misconduct proceedings.
- The project takes place in research settings and/or includes individuals actively engaged in or training for careers in research.
- The first phase specifies clear goals that will make the second phase possible.

For the second phase, ORI will invite those who were successful in receiving Phase I research funds to submit applications for research that builds on the preliminary findings from Phase I. It is understood that findings in Phase I may require investigators to modify their plans for Phase II from what was proposed in Phase I; modifications in scope or direction will need to be justified in Phase II applications.

Research Scope

Research institutions receiving funding from any of the HHS Public Health Service agencies are required by 42 C.F.R. Part 93.300(c) 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." Research supported by this announcement should address one or more aspects of this institutional obligation, and should

also build upon what has been learned in the social and behavioral sciences about human behavior.

Decades of research in the social and behavioral sciences has focused on when and why people are dishonest. This research has examined the effects of cognitive dissonance, self-concept maintenance, social identity, social networks, social approval, obedience, motivated forgetting, moral disengagement, among many other factors. Included in this research has been an appreciation of the importance of motivation, opportunity, norms, and social pressures.

Social and behavioral research specifically focused on criminology has sought to determine ways to prevent and deter dishonest activity that rises to the level of a criminal offense. Since the 1930s, criminologists interested in white collar crime have focused on factors/concepts such as differential association, anomie, strain, lack of self-control, attachment to or identification with the company/institution, low moral consensus, normalization or rationalization of deviance, and self-interest (rational choice theory). Recently, criminologists have been moving to integrate their theories to incorporate factors at all levels – individual, organizational, structural (e.g., laws and regulations) and cultural (e.g., degree of competitiveness) – to understand white collar crime.

To date, however, social scientists in these two broad areas of research have rarely partnered with those on the front lines of research misconduct – investigators in labs, in clinics and hospitals, and research integrity officials at universities. This partnering is essential because the research on research misconduct and integrity needs to be informed by the insights of those who have dealt with research misconduct and/or understand the pressures of working in basic science and clinical research. Understanding the additional pressures experienced by foreign

scientists in the United States, whose native languages are not English and who hold nonimmigrant visas, is critically important.

Research Objectives

To meet the aims outlined in this FOA, research is needed in the following areas. The listed areas of research are considered high priority, but this is not an exclusive list of potentially important research directions nor is it listed in order of priority. Research of the highest priority is that which can lead to interventions (including, but not limited to, education) that can prevent research misconduct.

- Studies to explore the utility of social and behavioral constructs and theories of behavior, related to factors at the individual, cultural, social and organizational levels, that might explain when and why individuals engage in research misconduct. These studies can focus on traditional perspectives or explore potentially new concepts that are inherent in the world of staff, students, post-docs, and principal investigators who work in research labs or other research settings. The research can use qualitative, quantitative or mixed methods.
- Studies to identify and test simple tools that can be used in Responsible Conduct of Research (RCR) education, lab meetings, and/or informal settings over time to successfully encourage researchers to avoid falsification, fabrication, plagiarism and questionable research practices, such as image beautification, deleting or ignoring outliers, error estimation instead of calculation, and filling in missing data.
- Studies to test the efficacy and/or effectiveness of formal behavior change interventions designed to stop individuals from engaging in research misconduct. These interventions

can include any combination of methods that have been shown to make it possible for people to avoid negative behaviors.

- Studies to identify social and cultural factors associated with falsification, fabrication, and plagiarism among staff, students, post-docs, and principal investigators working in research labs and other research settings. This could include, but is not limited to, qualitative research to understand how cultural norms for obedience, success, honesty, agreeableness (among other norms) interact with the competitive nature of the scientific enterprise, including pressure to publish in high impact journals, secure grant funding and invitations to speak at meetings, support staff employed through grant funding, etc.
- Studies to test the efficacy and/or effectiveness of support programs for staff, students, post-docs, and principal investigators who need assistance to avoid engaging in research misconduct. The programs tested need to have solid theoretical and empirical justifications and include ways to disseminate knowledge of and access to the program. These support programs can include, but are not limited to, institutional, community or web-based interventions at local, regional or national levels. Interventions can include peer support, official institutional support, hotlines, internet chat rooms or any other method that might encourage researchers tempted to engage in research misconduct or questionable research practices to seek help.
- Studies to document the challenges faced by whistleblowers at various levels in a research institution and the organizational and social factors that are necessary to facilitate reporting of misconduct and prevention of retaliation.
- Studies to investigate the efficacy and/or effectiveness of different types and/or combinations of incentives (individual and/or group) to encourage researchers at all

levels of experience to avoid questionable research practices that can lead to research misconduct, such as image beautification, deleting or ignoring outliers, error estimation instead of calculation, and filling in missing data. Particularly needed is research that will test educational interventions/programs/incentives that will increase the amount of monitoring and involvement of senior investigators in the process of mentoring junior scientists.

- Studies that examine practices used by research institutions to provide adequate support staff and IT resources and encourage faculty to participate in research misconduct proceedings. Misconduct proceedings can be burdensome on institutional resources, including staff and faculty time, general counsel commitment, and IT and security support for sequestration procedures. Faculty participation in misconduct proceedings also presents challenges related to conducting a proceeding that implicates a fellow faculty member. Qualitative research is encouraged that emphasizes what research institutions are doing well and how they can improve incentives and procedures to coordinate institutional resources more effectively and encourage faculty and staff to remain invested, empowered, and protected throughout a misconduct proceeding. Also encouraged is research that will identify factors that make the process particularly difficult for faculty and others involved in misconduct proceedings.
- Studies to investigate the consequences of questionable research practices and research misconduct, to explore the level and result of duplicate publication, manipulation of impact factors by journal editors and researchers, failure to adequately identify and mitigate financial and other conflicts of interest, and other practices that undermine the responsible conduct of research.

Authority

Section 301, Title III of the Public Health Service Act (42 U.S.C. §241 *et seq*.) authorizes the Secretary to make grants. On January 14, 1981, the Secretary delegated this authority to the Assistant Secretary for Health. On April 1, 2013, the Assistant Secretary for Health re-delegated this granting authority to the Director of the Office of Research Integrity.

II. AWARD INFORMATION

The ORI Research on Research Integrity Program intends to make available approximately $900,000 for competing grants. Grants will be funded in annual increments (budget periods) and will be generally approved for a project period of up to one year, although shorter project periods may be approved.

Award Information

Estimated Funds Available for Competition: $900,000

Anticipated Number of Awards: 10-12

Range of Awards: up to $75,000 direct costs per budget period (indirect costs additional)

Anticipated Start Date: 09/01/2015

Period of Performance: Not to exceed one year

Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted: Electronic via Grants.gov **ONLY unless an exemption is granted**

III. ELIGIBILITY INFORMATION

Eligible Applicants include:

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

- Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.
- Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

2. Cost Sharing or Matching: none

3. Responsiveness and Screening Criteria: none

Application Screening Criteria

All applications appropriately submitted will be screened to assure a level playing field for all applicants. If duplicate applications from the same organization for the same project are successfully submitted, only the last application received by the deadline will be reviewed. Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via www.grants.gov (unless an exemption was granted 2 business days prior to the deadline) by April 20, 2015.
2. The Project Narrative section of the application must be double-spaced, on the equivalent of 8½" x 11" page size, with 1" margins on all sides (top, bottom, left and right) and font size not less than 12 points.
3. The Project Narrative must not exceed 20 pages. NOTE: The following items do not count toward the page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary and Budget narrative.

4. The total application including Appendices must not exceed 45 pages. NOTE: items noted above do not count toward total page limit.
5. Proposed budget does not exceed maximum indicated in Range of Awards.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Information to Request Application Package

Application packages may be obtained electronically by accessing Grants.gov at http://www.grants.gov. If you have problems accessing the application or difficulty downloading, contact:

Grant Operations Center, Office of Grants Management Operations Center, telephone 1-888-203-6161, or e-mail ASH@LCGnet.com.

2. Content and Form of Application Submission

Letter of Intent

Prospective applicants are asked to submit a letter of intent as early as possible, but no later than 5:00 P.M. E.S.T., March 1, 2015. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows HHS/OASH to estimate the potential review workload and plan the review. The letter of intent should be sent to the address listed under the AGENCY CONTACTS section below. The letter of intent should include a descriptive title of the proposed project, the name, address and telephone number for the designated authorized representative of the applicant organization, and the FOA number and title of this announcement.

Application Format

Applications must be prepared using forms and information provided in the online grant application package. **The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Screening Criteria. Project Narrative pages must be double-spaced.**

The applicant should use an easily readable typeface, such as Times New Roman or Arial, 12-point font. Tables may be single spaced and use alternate fonts but must be easily readable. The page limit does not include budget, budget narrative/justification, required forms, assurances, and certifications as described in Application Screening Criteria. All pages, charts, figures, and tables, whether in the narrative or appendices, should be numbered. Applications that exceed the specified page limits when printed on 8.5" x 11" paper by HHS/OASH/OGM will not be considered. We recommend that applicants print out their applications before submitting electronically to ensure that they are within the page limit and are easily readable.

Appendices

Appendices should include any specific documents outlined in the Application Content section of this FOA. If not specified, appendices may include curriculum vitae, organizational structure, examples of organizational capabilities, or other supplemental information which supports the application. Brochures and bound materials should not be submitted. Appendices are for supportive information only and should be clearly labeled. All information that is critical to the proposed project should be included in the body of the application. Appendices created specifically for the application should use the same formatting required for the Project Narrative,

including double-line spacing. However, appendix documents that were not created directly in response to this funding announcement, especially those imported from other sources and documents, may use other formatting but must be easily readable (e.g., organizational structure).

Project Abstract

Applicants 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. Abstracts may be published by HHS/OASH and should not include sensitive or proprietary information.

Budget Narrative

The Budget Narrative text 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.

Electronic Submission

The HHS Office of the Assistant Secretary for Health (HHS/OASH) requires all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, *will not* be accepted for review.

You may access the Grants.gov website portal at http://www.grants.gov. All HHS/OASH funding opportunities and grant application packages are made available on Grants.gov.

Applications will not be considered valid until all application components are received via Grants.gov by the HHS/OASH Office of Grants Management according to the deadlines

specified in the DATES section on page 1 of this announcement. Application submissions that do not adhere to the due date and time requirements will be deemed ineligible.

Applicants are encouraged to initiate electronic applications early in the application development process. This will aid in addressing any problems with submissions prior to the application deadline. Any files uploaded or attached to the Grants.gov application must be of the following file formats – Microsoft Word, Excel or PowerPoint, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only). Even though Grants.gov allows applicants to attach any file format as part of their application, HHS/OASH restricts this practice and only accepts the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format identified above will not be accepted for processing and will be excluded from the application during the review process. The application must be submitted in a file 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. Page cannot be reduced in size, resulting in multiple pages on a single sheet, to avoid exceeding the page limitation. All documents that do not conform to the above will be excluded from the application during the review process.

A. Important Grants.gov Information

You may access the electronic application for this program on http://www.grants.gov. You must search the downloadable application page by the Funding Opportunity Announcement number or CFDA number.

To ensure successful submission of applications, applicants 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.

Applicants should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov.

- You are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. 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.
- Instructions are available on the Grants.Gov web site as part of the organization registration process at http://www.grants.gov/web/grants/applicants/organization-registration.html.
- All applicants must register in the System for Account Management (SAM)). You should allow a *minimum* of five days to complete the SAM registration. Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations. You can register with the SAM online and it will take about 30 minutes (https://www.sam.gov.)
- You must renew your SAM registration each year. Organizations registered to apply for Federal grants through http://www.grants.gov will need to *renew* their registration in SAM.
- It may take 24 hours or more for SAM updates to take effect in Grants.gov, so potential applicants should ***check for active registration well before the application deadline.***
- Applicants must maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an HHS agency.

An award cannot be made until the applicant has complied with these requirements. In accordance with 2 C.F.R. 25.205, at the time an award is ready to be made, if the intended recipient has not complied with these requirements, HHS/OASH:

- May determine that the applicant is 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 the recipient makes a sub-award.

B. Application Content

Successful applications will contain the following sections:

Project Narrative

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 a grant 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:

- Executive Summary
- Problem Statement
- Goal(s) and Objective(s)
- Proposed Intervention
- Special Target Populations and Organizations
- Outcomes
- Project Management
- Evaluation

- Dissemination
- Organizational Capability
- Responsible Conduct of Research Plan

Executive Summary: This section should include a brief description of the proposed project, including: goal(s), objectives, outcomes, and products to be developed.

Problem Statement: This section should describe, in both quantitative and qualitative terms, the nature and scope of the specific and particular problem or issue, and the proposed intervention it is designed to address. It should detail how the project will potentially affect the targeted population, specific subgroups within those populations, and other interested stakeholders as identified. It is recommended that applicants focus their problem statement on the specific aspects of the history, extant literature, current status, and policy considerations bearing on the program area, and the roles of the national, state, and local agencies responsible for their operation, rather than providing a broad or sweeping historical overview that is not directly related to the proposed interventions and activities.

Goals and Objectives: This section should consist of a description of the project's goal(s) and major objectives. Unless the project involves multiple, complex interventions, we recommend you have only one overall goal.

Proposed Intervention: This section should provide a clear and concise description of the intervention you are proposing to use to address the need identified in the program announcement and the problem described in the "Problem Statement" above. Applicants are expected to explain the rationale for using a particular intervention and to present a clear connection between identified system gaps and needs and the proposed activities. Proposals should detail the nature of the activities to be undertaken, how they address system gaps and

identified issues, and how they will assist in achieving the overall project goals and objectives. Clarification as to why these specific activities were selected is appropriate (i.e., Has this approach been successful in other settings? Does previous research suggest this direction?). Also note any major barriers you anticipate encountering and how your project will be able to overcome those barriers. At a minimum, applicants should:

1. Indicate a plan for addressing the problems or issues nationally. Provide detailed descriptions of specific products or outcomes proposed for development or modification.
2. Demonstrate how technology will be incorporated to advertise and advance programs and services, provide training and/or technical assistance, and disseminate information and products.
3. Describe the role and composition of potential subrecipients who are intended to be involved in completing specific tasks, and identify the percentage of level of effort subrecipients are anticipated to provide in completing programmatic activities.
4. Provide specifics about the intervention strategies, expected outcomes, barriers, and alternate approaches.

Special Target Populations and Organizations: This section should describe how you plan to involve community-based organizations in a meaningful way in the planning and implementation of the proposal project. This section should also describe how the proposed intervention will target disadvantaged populations, including limited-English speaking populations. Additionally, this section should identify potential stakeholders and outline plans to engage stakeholders in the project.

Outcomes: This section of the project narrative must clearly identify the measurable outcome(s) that will result from the project. HHS/OASH will not fund any project that does not include

measurable outcomes. In addition to discussion in the narrative, applicants must describe how they envision the project will benefit the field at large. A "measurable outcome" is an observable end result that describes how a particular intervention benefits intended recipients.

This section should describe the specific outcomes, while the Evaluation section should emphasize the outcomes will be measured and reported. Your application will be scored on the clarity and nature of your proposed outcomes, not on the number of outcomes cited. In many cases, it may be appropriate for a project to have only one outcome.

Project Management: This section should include 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. It should 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. It should also describe the approach that will be used to monitor and track progress on the project's tasks and objectives. HHS/OASH expects that, throughout the grant period, the Project Director will have involvement in, and substantial knowledge about, all aspects of the project.

Evaluation: This section should describe the methods that you will use to evaluate whether the proposed intervention achieves its measurable outcome(s) and assess and evaluate the "impact" of proposed activities. You should describe the quantitative and qualitative tools and techniques that you will employ to measure the outcome(s) and how you will identify and document the "lessons learned."

Dissemination: This section should 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 other parties who might be interested in using the results

of the project. All appropriate findings and products will be posted on a website sponsored by HHS/OASH as determined by the HHS/OASH project officer. Therefore, applicants should propose other innovative approaches to informing parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project. HHS/OASH expects that nationwide dissemination of products and knowledge will occur.

Organizational Capability: Each application must include an organizational capability statement and curriculum vitae for key project personnel. The organizational capability statement should describe how the applicant agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. This description should cover capabilities of the applicant agency not included 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 organizational chart showing the relationship of the project to the current organization. Also 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.

Responsible Conduct of Research Plan: Plans to ensure that all personnel involved in the project have acquired training in the responsible conduct of research should be described. This includes, but is not limited to, training in the pertinent federal, state, and local regulations (conflicts of interests, use of human subjects, research misconduct) and institutional policies (authorship and publication, data management, peer review, and research collaborations) relevant to the proposed project.

Budget Narrative

You are required to submit a detailed Budget Narrative for the 12-month period of the grant. ***Please Note:*** Because the proposal must demonstrate a clear and strong relationship between the stated objectives, project activities, and the budget, the budget justification should describe the ***cost estimated per proposed project, activity, or product***. This budget justification should define the amount of work that is planned and expected to be performed and what it will cost. The Budget Narrative does not count toward your total application page limit.

Appendices

Work Plan. The Project Work Plan should reflect, and be consistent with, the Project Narrative and Budget, and must cover the duration of the project period. The 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, action step, or product, the work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task.

Letters of Commitment from Subrecipient Organizations and Agencies

Letters of Commitment are required 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. Applicants should NOT provide letters of "support," and letters of support such as this will not be considered during the review.

3. Submission Dates and Times

The deadline for the submission of applications under this announcement is **5:00 p.m. Eastern Time on the date indicated in the DATES section on page 1 of this announcement.** Applications must be submitted by that date and time.

Applications that fail to meet the application due date will not be reviewed and 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 http://www.grants.gov. Grants.gov can take up to 48 hours to notify you of a successful submission.

Unsuccessful submissions will require authenticated verification from http://www.grants.gov indicating system problems existed at the time of your submission. For example, you will be required to provide an http://www.grants.gov submission error notification and/or tracking number in order to substantiate missing the cut off date.

4. 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.

5. Funding Restrictions

The allowability, allocability, reasonableness and necessity of direct and indirect costs may be charged to HHS/OASH grants in accordance with Department regulations and policy effective at the time of the award. Current requirements are outlined in the following documents: 2 C.F.R. § 220 (OMB Circular A- 21, for Institutions of Higher Education); 2 C.F.R. § 225 (OMB Circular A–87, for State, Local, and Indian Tribal Governments); 2 C.F.R. § 230 (OMB Circular A–122, for Nonprofit Organizations); and 45 C.F.R. Part 74, Appendix E (Hospitals). Copies of the Office of Management and Budget (OMB) Circulars are available on the Internet at http://www.whitehouse.gov/omb/circulars.

In order to claim indirect costs as part of a budget request, an applicant must have an indirect cost rate which has been negotiated with the Federal Government or a documented plan, in accordance with the applicable policy and regulation. The Health and Human Services Division of Cost Allocation (DCA) Regional Office that is applicable to your state can provide information on how to receive such a rate. A list of DCA Regional Offices is included in the grant application package for this announcement.

Pre-Award Costs:

Pre-award costs are not allowed.

Salary Limitation:

The Consolidated Appropriations Act, 2014 (P.L. 113-76), and the subsequent Continuing Resolution for FY 2015 (P.L. 113-164), limits the salary amount that may be awarded and charged to HHS/OASH grants and cooperative agreements. Award funds should not be budgeted to pay the salary of an individual at a rate in excess of Executive Level II. Currently, the Executive Level II salary of the Federal Executive Pay scale is $181,500. This

amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under an HHS/OASH grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is $350,000 per year plus fringe benefits of 25% ($87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to $181,500, their direct salary would be $90,750 (50% FTE), fringe benefits of 25% would be $22,687.50, and a total of $113,437.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual's *actual* base full time salary: $350,000 50% of time will be devoted to project	
Direct salary	$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 limitation: Individual's base full time salary *adjusted* to Executive Level II: $181,500 50% of time will be devoted to the project	
Direct salary	**$90,750**
Fringe (25% of salary)	**$22,687.50**
Total amount	**$113,437.50**

Appropriate salary limits will apply as required by law.

V. APPLICATION REVIEW INFORMATION

1. Criteria: Eligible applications will be assessed according to the following criteria:

   Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

   a. **Significance (Weight: 15 points)**

      Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Will the project significantly advance the defined objectives? Does the study have clear relevance to biomedical, behavioral health sciences, and/or health services research? Does the application address the societal, organizational, group, or individual factors that affect integrity in collaborative research?

   b. **Investigator(s) (Weight: 15 points)**

      Are the PD/PIs, collaborators, and other researchers well suited to the project? If early stage investigators or new investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Is their leadership approach, governance, and organizational structure appropriate for the project? Have the investigator and team members demonstrated acceptable levels of

face-to-face training in the responsible conduct of research? If the project is collaborative, do the team members have complementary and integrated expertise? If the investigator is a junior investigator (early career stage), has a mentoring plan been established to ensure his or her success in implementing the proposed project?

c. **Innovation (Weight: 20 points)**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

d. **Approach (Weight: 25)**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are there plans for (1) protection of human subjects from research risks, and (2) inclusion of minorities and members of both sexes/genders as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Are the methods clearly described? Have the researchers demonstrated feasibility of the study? Are surveys and/or other test instruments adequately described and appropriate to the study? Are survey cohorts appropriate for the study and clearly identified? Can the researchers gain access to the

data and/or populations they are proposing to study? Will the study yield data that are strong and informative? Will the study lead to future investigations on research integrity? Have the researchers fully explored prior research and explained how their work will build on or advance that research? For applications designating multiple investigators, does the leadership plan ensure that there will be sufficient coordination and communication among the investigators?

e. **Final Product (Weight: 15 points)**

Is there a clear description of the expected product at the end of the project period? Is it realistic and consistent with the objectives and purpose of this FOA? Is the anticipated outcome/product likely to be achieved and will it significantly benefit the field of research integrity?

f. **Budget (Weight: 10 points)**

Is the budget justified with respect to the adequacy and reasonableness of resources requested? Is the budget appropriate for the scope of work described? Are budget line items clearly delineated and consistent with the narrative, specific aims, and work plan?

g. **Protections for Human Subjects**

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 C.F.R. Part 46, the review panel will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: (1) risk to subjects; (2) adequacy of protection against risks; (3) potential benefits to the subjects and others; (4) importance of the knowledge to be gained; and, (5) data and safety monitoring for clinical trials. For research that involves human

subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 C.F.R. Part 46, the committee will evaluate: (1) the justification for the exemption; (2) human subjects involvement and characteristics; and, (3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Human Subjects Protection and Inclusion Guidelines: (http://www.hhs.gov/ohrp/policy/engage08.html)

2. Review and Selection Process

Each HHS/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 pass the screening and meet the responsiveness criteria if applicable. 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 V.1, the reviewers will comment on and score the applications, focusing their comments and scoring 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.
Final award decisions will be made by the Director of the Office of Research Integrity.

Review of Risk Posed by Applicant

The HHS/OASH will evaluate each application in the fundable range for risks posed by an applicant before issuing an award in accordance with 45 C.F.R. Part 75.205. This evaluation may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If HHS/OASH determines that a Federal award will be made, special conditions that

correspond to the degree of risk assessed by the applicant will be applied to the Federal award. OASH will use a risk-based approach and may consider any items such as the following:

(1) Applicant's financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is 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;

(4) Reports and findings from audits performed; and,

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

3. Anticipated Announcement and Award Dates

HHS/OASH seeks to award funds as much in advance of the estimated project start date shown in Section II "Award Information," as practicable, with a goal of 10-15 days.

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The HHS Office of the Assistant Secretary for Health does not release information about individual applications during the review process. If you would like to track your application, please see instructions at http://www.grants.gov/web/grants/applicants/track-my-application.html. The official document notifying an applicant that a project application has been

approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH Office of Grants Management. Successful applicants will receive this document via system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount of money awarded, the purposes of the grant, the anticipated length of the project period, terms and conditions of the grant award, and the amount of funding to be contributed by the grantee to project costs, if applicable. Grantees should pay specific attention to the terms and conditions of the award as indicated on the NOA, as some may require a time-sensitive response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the grant.

Unsuccessful applicants will be notified by the program office by e-mail and/or letter and will receive summary comments pertaining to the application resulting from the review process. On occasion, some applicants may receive a letter indicating that an application was approved but unfunded. These applications are 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

In accepting the grant award, the grantee stipulates that the award and any activities thereunder are subject to all provisions of 45 C.F.R. Parts 74 and 92, currently in effect or implemented during the period of the grant or other Department regulations and policies effective at the time of the award.

In addition, recipients must comply with all terms and conditions outlined in their grant awards, the Department of Health and Human Services (HHS) Grants Policy Statement, 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.

Grant funds may only be used to support activities outlined in the approved project plan. The successful applicant will be responsible for the overall management of activities within the scope of the approved project plan in accordance with applicable laws and regulations.

Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all grant 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.

Acknowledgement of Funding

Federal grant support must be acknowledged in any publication developed using funds awarded under this program. All publications developed or purchased with funds awarded under this program must be consistent with the requirements of the program. Pursuant to 45 C.F.R. § 74.36(a), HHS may reproduce, publish, or otherwise use materials developed under this grant for Federal purposes, and may authorize others to do so.

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). For the full text of the award term, see http://www.hhs.gov/opa/grants/trafficking_in_persons_award_condition.html. If you are unable

to access this link, please contact the Grants Management Specialist identified in this funding opportunity announcement to obtain a copy of the term.

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 http://dhhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html.

Pilot Whistleblower Protection

A standard term and condition of award will be in the final notice of award; all applicants will be subject to a term and condition that applies the terms of 48 C.F.R. Part 3, section 3.908, to the award, and requires that grantees inform their employees in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

Same-sex Spouses, Marriages, and Households

A standard term and condition of award will be included in the final NOA that states: "In any grant-related activity in which family, marital, or household considerations are, by statute or regulation, relevant for purposes of determining beneficiary eligibility or participation, grantees must treat same-sex spouses, marriages, and households on the same terms as opposite-sex spouses, marriages, and households, respectively. By "same-sex spouses," HHS means individuals of the same sex who have entered into marriages that are valid in the jurisdiction where performed, including any of the 50 states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "same-sex marriages," HHS means marriages between two individuals validly entered into in the jurisdiction where performed, including any of the 50

states, the District of Columbia, or a U.S. territory or in a foreign country, regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. By "marriage," HHS does not mean registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage.

Programmatic Reporting

Quarterly progress reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

A final progress report covering the entire project period is due 90 days after the end of the project period. Final reports must be submitted by upload to our grants management system (GrantSolutions.gov), in the Grant Notes module.

Financial Reporting

Grantees are required to submit quarterly and annual Federal Financial Reports (FFR) (SF-425). Reporting schedules will be issued as a condition of grant award. A final FFR covering the entire project period is due 90 days after the end of the project period. FFRs must be submitted via upload to our grants management system (GrantSolutions.gov), in the FFR module.

Quarterly cash reporting to the HHS Payment Management System on the FFR is also required. Please note these FFR reports are separate submissions via the Division of Payment Services. At this time, data is not transferable between the two systems and you will report twice on certain data elements. Grantees receiving $500,000 or greater of Federal funds must also undergo an independent audit in accordance with OMB Circular A-133 or regulations and policy effective at the time of the award.

FFATA and FSRS Reporting

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

VII. AGENCY CONTACTS

Administrative and Budgetary Requirements and Program Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH Office of Grants Management:

Roscoe Brunson
Grants Management Specialist
1101 Wootton Parkway, Suite 550
Rockville, MD 20852
Telephone: 240-453-8822
E-Mail: Roscoe.Brunson@hhs.gov

For information on program requirements, contact the program office:

Ann A. Hohmann, Ph.D., M.P.H.
Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, MD 20852
Telephone: 240-453-8431
E-Mail: Ann.Hohmann@hhs.gov

VIII. OTHER INFORMATION

Application Elements

Application for Federal Assistance (SF-424)

Budget Information for Non-construction Programs (SF-424A)

Budget Narrative

Assurances for Non-construction Programs (SF-424B)

Disclosure of Lobbying Activities (SF-LLL)

Project Abstract Summary

Project Narrative

Appendices

Zoe H. [illegible] for Dr. Don Wright 4 March 2015

Don Wright, M.D., M.P.H. Date
Acting Director
Office of Research Integrity
U.S. Department of Health and Human Services