U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response

Funding Opportunity Announcement and Grant Application Instructions

Funding Opportunity Title: Assistant Secretary for Preparedness and Response Grants to Support Scientific Research Related to Recovery from Hurricane Sandy

Funding Opportunity Number: EP-HIT-13-001

Catalog of Federal Domestic Assistance (CFDA) Number: 93.095

FY 2013

Table of Contents

- I. FUNDING OPPORTUNITY DESCRIPTION
- II. AWARD INFORMATION
- III. ELIGIBILITY INFORMATION
- IV. APPLICATION AND SUBMISSION INFORMATION
- V. APPLICATION REVIEW INFORMATION
- VI. AWARD ADMINISTRATION INFORMATION
- VII. AGENCY CONTACTS
- VIII. OTHER INFORMATION

ATTACHMENTS

Attachment A: Instructions for Completing Required Forms Attachment B: Budget Narrative/Justification – Page 1 – Sample Format Attachment C: Project Work Plan, Page 1 – Sample Template Attachment D: Instructions for Completing the Project Summary/Abstract Attachment E: Insurance Statement Attachment F: Potentially Applicable Public Policy Requirements Attachment G: Research and Related Project Information

U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) Office of Policy and Planning

Announcement Type: New funding opportunity.

Funding Opportunity Number: EP-HIT-13-001

Catalog of Federal Domestic Assistance (CFDA) Number: 93.095

Dates: All applications must be submitted by 05/20/2013

I. FUNDING OPPORTUNITY DESCRIPTION

Statutory Authority

Disaster Relief Appropriations Act of 2013 (Public Law 113-2).

SUMMARY and Project Overview

This Funding Opportunity Announcement (FOA) provides funds from the Disaster Relief Appropriations Act of 2013. The Office of the Assistant Secretary for Preparedness and Response (ASPR) is requesting applications for research that will inform the ongoing response to, and recovery from, Hurricane Sandy. Much important scientific research can only be done during the response to and recovery from an emergency or a major disaster, or the window of opportunity is lost. In the aftermath of Hurricane Sandy, there has been an acknowledged and urgent need for public health research. To identify the needs for this research, subject matter experts were rapidly convened at the New York Academy of Medicine on November 16, 2012. At this meeting, a number of topical areas and research questions were identified, including those that, if addressed, would be able to impact on recovery as well as future preparedness. These areas include the broad areas of resiliency, decision making, the health system response, adverse health outcomes (including behavioral health), communications, and the use of social media. A meeting summary can be found at http://www.nyam.org/news/nyam-news/2013-03-06-1.html.

Based on the outcomes from the New York meeting, ASPR performed its own assessment of research needs, and ASPR is now requesting proposals for research to be conducted in key prioritized areas which also coincide with ASPR's mission. Research designs for surveys, behavioral health studies, and other experiments that can inform the response to and recovery from Hurricane Sandy without interfering with vital assistance to families and communities will be considered. This research is specifically intended to inform long-term recovery efforts from Hurricane Sandy. So that these results can impact long-term recovery from Hurricane Sandy, grantees are encouraged to share their collected data broadly with the research community. CDC is issuing a separate but similar FOA which can be accessed at grants.gov.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s).

Overarching Goal, Objectives, and Activities:

Under this proposed grant announcement, the overarching goal of HHS is to:

Goal: Protect Americans' health and safety during emergencies and foster resilience in response to emergencies

ASPR's Government Performance and Results Act goals note that "HHS will work with its Federal, state, local, tribal, and international partners to build community resilience and strengthen health and emergency response systems. Robust systems are essential to a secure and resilient Nation with required capabilities to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk. This includes strengthening the Federal medical and public health response capability." Scientific research involved with preparedness and response is a key component of this endeavor.

Some of the priority needs for research funding include, but are not limited to:

Assess community resilience and identify resilience factors to inform recovery

- How can we predict/target/promote resilience for those in communities affected by Sandy? How does the social connectedness (or social capital) present in a community predict resilience and positive recovery outcomes? What are the factors that contribute to enhanced resilience of one group of communities or individuals in the aftermath of Sandy vs. others and why?
- What are the factors that impact individual and community resilience (by population subgroup) and policy impact?

What interventions or policy decisions -either before the event or during response and recovery periodpromoted, or can promote throughout long-term recovery, resilience and better outcomes? For what populations?

Evaluate the effectiveness of risk communication and use of social media

- What were the most critical information needs people had before, during, and after the storm hit, as well as throughout recovery? How and when were social media and mobile devices used to access health and safety-related information? For which functions, under what circumstances, and for which populations, was social media most effective, and which approaches just created additional 'noise' in the system without leading to better outcomes?
- Did information reach traditionally vulnerable populations (e.g., those with limited English proficiency, homeless, elderly, disabled, etc.)? If so, how did they access information and were their information needs met? If not, what critical needs were unmet that can be targeted in long-term recovery efforts?

Substantial efforts were made to establish local IT networks to help people communicate and access resources. Is there any evidence that they were effective in promoting well being, resilience or recovery?

How can effective risk communication be harnessed for recovery for these affected communities in the recovery period?

Evaluate the health system response and health care access discontinuity to assist recovery

How were various components of the health care system (primary care, ambulatory care, specialty care, emergency care, long term care, home care, etc.) affected during the response and recovery? How can this information be used to inform long-term recovery efforts?

How was the medical supply chain impacted, and what were the key supply chain issues that led to resilience of the health care system or interruptions in the delivery of critical health care services? What are potential short and long-term interventions that can support long-term Sandy recovery?

How were access and utilization of critical health care services (e.g. dialysis, chemotherapy, etc.) affected by Sandy and were there negative health consequences due to interruptions of these services that could be addressed in long-term recovery efforts?

- What impact or potential adverse outcomes may have resulted from delays in or reduced access to prescription refills and replacement of durable medical equipment (e.g. 02 concentrators, electric wheelchairs, e.tc.) for at-risk and medically vulnerable populations? What interventions can be readily made to both assist long-term recovery and include in preparedness activities to prevent similar issues in the event of another public health emergency or disaster?
- Can claims data be used to return a quantitative assessment of a health care facility operating status and surge capacity that informs recovery efforts for these facilities?

Evaluate evacuation and policy decision-making and outcomes

- What types of evacuation recommendations were most effective in influencing decisions? What elements of those recommendations, including factors such as the source or speaker, timing, and language,
- enhanced the message impact and can be used to inform messaging throughout long-term recovery?
 What were the health outcomes among persons in affected communities who evacuated compared to those who sheltered-in-place which can inform long-term recovery for those individuals and communities?
- How did policy makers and administrators of health care facilities make decisions related to evacuation, or other important policy decisions? What information did they use? What other factors influenced them which can be used to inform long-term recovery decision-making?

Evaluate and mitigate mental health outcomes of affected individuals and communities

- Were any intervention strategies effective in preventing short- or long-term sequelae of disasters? How did disaster assistance support at-risk populations and their long-term recovery? What intervention strategies would be useful throughout long-term recovery?
- How did Sandy impact at-risk individuals' access to mental health facilities, service utilization and treatment patterns and were there adverse outcomes that can be addressed in future long-term recovery interventions?
- What potential adverse outcomes resulted from the decision to evacuate a mental health care facility or other healthcare facility that provides mental health treatment (e.g., mental health unit in a hospital) compared to those that sheltered in place? Were adverse outcomes different for those that were evacuated to: shelters, similar mental/healthcare facilities, or more restricted facilities (due to lack of available beds at other facilities)?

The project narrative must contain the following:

- Applicant identifies the specific public health threats, risks, or other important issues that will be addressed with this funding and proposes strategies designed to reduce/mitigate the threats and risks, or addresses particular aspects of the recovery from Hurricane Sandy.
- Applicant provides a plan for sharing, as applicable, their de-identified, documented, and geographically coded data as well as the scientific results, broadly with the research community.
- If human subjects will be used in research, applicants must make provisions for protocols, appropriate consent and Institutional Review Board (IRB) approvals. NOTE: in the event that rapid, national-level IRB approval is required, the IRB review may be provided by the National Institutes of Health, who are responsible for managing the Public Health Emergency Review Board (PHERRB). Applicants should make provision for IRB related materials, consent forms, etc., whether in draft or already-approved format. Those unapproved at the time of submission will need provision of IRB approval prior to award. Applicants should note if the research is exempt from IRB review within the appropriate exemptions listed in the Common Rule. All IRB requirements must be addressed before the onset of the project.

II. AWARD INFORMATION

Total Project Cost: **Project costs should not exceed \$500,000 in direct costs. Indirect or Facilities and Administration** (F&A) costs are allowed at the negotiated rate that was approved by the federal cognizant agency. Submit copy of current negotiated rate agreement.

Total Funding Amount: \$7.6 Million

Anticipated Number of Awards: 10-15 grants

Project Period Length: 24 months after issue date – all project activities must be completed within the stated project periods –extensions on project dates will not be granted

Budget Period Length: 24 months after issue date – all funds must be expended¹ by end of the 24 month period.

Ceiling of Individual Award Range: up to \$500,000 direct costs. Indirect costs are allowed submit negotiated indirect cost rate agreement.

Anticipated Start Date: August 15, 2013

Expected Duration of Support: 24 months – no draw-downs from PMS may be made outside of the 24 month period and no costs may be paid outside of the 24 month period.

Type of Application Sought: Grant

ASPR Responsibilities

The ASPR/Office of Policy and Planning will be responsible for the review and approval of program activities including, but not limited to, ensuring that funds are used and activities are conducted in accordance with the terms and conditions of the award. ASPR will also approve timelines and review progress of the program as well as monitor reporting requirements.

Applications and progress will be assessed by a review committee of subject matter experts from ASPR, CDC, NIH, or other Federal partners, as needed, based on proposal content. The evaluation will include the assessment of impact on recovery from Hurricane Sandy, goals, objectives, outputs, timelines and milestones and the oversight of proposed activities through semi-annual reports and on-site visits, as needed.

HHS – ASPR Activities:

Review all projects for potential funding.

Review and approve the awardee's annual work plan, detailed budget, and monitoring-and-evaluation plan. Meet in approximately one year after the award date with all awardees under this announcement, along with national health officials, to assess, review, and validate progress and accomplishments, in light of the contemporaneous state of recovery from Hurricane Sandy.

¹ Expend – for purposes of this FOA this term includes both obligation and outlay of funds. Awarded funds are distributed through the Payment Management System (PMS). No draw-downs from PMS may be made outside of the 24 month period and no costs may be paid outside of the 24 month period.

Collaborate with the awardees on designing and implementing the activities listed above, including, but not limited to, the provision of technical assistance to develop program activities, data management and analysis, quality assurance, the presentation and possibly publication of program results and findings, and the management and tracking of finances.

Conduct financial and administrative capability assessments of applying and/or awarded institutions.

Awardee Responsibilities

Awardee will be responsible for coordinating activities approved under the award. Prior to awarding the Grant, the awardee will be responsible for developing achievable programming activities. The awardee will also be responsible for tracking all activities and processes, following the terms and conditions of the grant, and satisfactorily adhering to budget and Monitoring and Evaluation (M&E) reporting plans. Awardee will compile program results from subrecipient (contracts and grants) affiliates into consolidated semi-annual and annual reports.

Once a grant award is in place, requests to modify or amend it or the work plan must be approved by the ASPR Grants Management Officer upon review and acceptability from the ASPR program official, and should be within the scope of the original project.

All awardees that receive funding under this announcement will be expected to meet at the end of one year from the date of award with ASPR staff, to assess overall progress, share research results, data and outcomes, particularly in light of the current state of recovery from Hurricane Sandy. Grantees may use grant funds for supporting their travel to this meeting. Use of grant funds should be included in the budget section of the applications.

The following is a summary of the annual program requirements for awardees:

- Submit all required funding application components, including project narratives, work plans, and budgets as outlined in Section IV, with an emphasis on short-term and long-term plans to address how the research overall will impact Hurricane Sandy recovery, without interfering with the ongoing response.
- Submit required progress reports and program and financial data, including progress toward bridging projectrelevant gaps that have been identified. The report should describe how the outcomes or project deliverables will be tracked and/or evaluated. Reports must describe the activities that were conducted with grant funds, the purposes for which these funds were spent and the recipients of the funds; the extent to which the awardee has met stated goals and objectives; and the extent to which funds were expended consistent with the awardee's funding application.

Have in place fiscal and programmatic systems to document accountability and improvement.

Awardees will comply with Health Insurance Portability and Accountability Act (HIPAA) and IRB requirements as applicable.

III. ELIGIBILITY INFORMATION

Eligible Applicants

Eligible applicants that can apply for this funding opportunity are listed below. ASPR encourages collaborative efforts, or applications from research teams or consortia. Although eligible institutions are not restricted to those in areas

directly affected by Hurricane Sandy, applicants are expected to have the ability to perform work onsite in those affected communities as warranted, and have collaborations in place with the affected areas and communities.

Nonprofit with 501C3 IRS status (other than institution of higher education)
Nonprofit without 501C3 IRS status (other than institution of higher education)
For-profit organizations (other than small business)
Small, minority, and women-owned businesses
Universities
Colleges
Research institutions
Hospitals
Community-based organizations
Faith-based organizations
Federally recognized or state-recognized American Indian/Alaska Native tribal governments
American Indian/Alaska native tribally designated organizations
Alaska Native health corporations
Urban Indian health organizations
Tribal epidemiology centers
State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

Political subdivisions of States

Geographic Restrictions – Benefits of this project must be restricted to the FEMA declared major disaster states, which are: Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, West Virginia, or District of Columbia.

Insurance: Applicants are required (see Attachment E) to attest that funds requested will not be used for costs that are reimbursed by the Federal Emergency Management Agency (FEMA), under contract for insurance or by self-insurance.²

Awards will not be made to an organization on the Excluded Parties Lists or who has debt owed to the federal government.

Persons on the Excluded Parties Lists may not receive payment from these funds.

² Self-insurance is a formal plan, pursuant to law or regulation, in which amounts are set aside in a fund to cover losses of specified types and amounts, typically by a commercial insurance company. Appropriated funds are precluded from expenses that are or can be reimbursed by the formal self-insurance plan.

Cost Sharing or Matching:

There is no cost sharing or match requirement for this project.

Maintenance of Effort/Funding:

Maintenance of Effort/Funding is not required for this program.

Mandatory Meetings:

If awarded, grantee is required to attend a meeting in Washington DC.

Screening and Responsiveness Criteria

Application Screening Criteria

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 http://www.grants.gov by May 20, 2013 at 9:00 PM. If applicant is providing a letter of intent, it must be submitted electronically by April 22, 2013.
- 2. The Project Narrative section of the Application must be **double-spaced**, on 8 $\frac{1}{2}$ " x 11" plain white paper with 1" margins on both sides, and a font size of not less than 11.
- 3. The Project Narrative must not exceed 15 pages. NOTE: The Project Work Plan, Letters of Commitment, budget narrative and justification forms, attestation statement, Vitae of Key Project Personnel and Other Relevant Annexes are not counted as part of the Project Narrative for purposes of the 15-page limit.

Application Responsiveness Criteria

Applications that do not meet the following responsiveness criteria will be administratively eliminated and will not be reviewed:



Applications submitted after the due date and time will not be reviewed.

Applications submitted by non-eligible entities will not be reviewed.

Applications submitted by individuals will not be reviewed.

Applications addressing geographic locations outside the restricted areas listed above will not be reviewed.

Applications not including the required attestation statement.

Applications failing to include the required forms will not be reviewed.

ASPR will not accept applications with a Project Narrative that exceeds 15 pages.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

Application materials can be obtained from <u>http://www.grants.gov</u>.

Applicants are strongly encouraged to send a letter of intent to the program office by April 22, 2013, outlining the project abstract and approximate funding request. Letters of intent should be sent to:

Jessica Tucker Jessica.tucker@hhs.qov

Required registrations:

Central Contractor Registration (CCR) and Data Universal Numbering System (DUNS) Requirements:

Except for those entities exempt from requirements listed at <u>2 CFR Part 25</u> (e.g., individuals), effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive Federal grant funds from any HHS Operating/Staff Division (OPDIV) or receive subawards directly from recipients of those grant funds to:

Be registered in the CCR prior to submitting an application of plan;

Maintain an active CCR registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV; and

Provide its DUNS number in each application or plan it submits to the OPDIV.

An award cannot be made until an applicant has complied with these requirements. At the time an award is ready to be made, if the intended recipient has not complied with these requirements, the OPDIV:

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.

Additionally, all first-tier subaward recipients (i.e., direct subrecipient) must have a DUNS number at the time the subaward is made.

CCR registration may be made online at https://www.sam.gov/portal/public/SAM/

Grants.gov registration – All entities must register and/or renew registration with grants.gov prior to submitting an application. Grantees previously registered must assure that the registration is still valid and up-to-date. Registration and re-registration may take up to 10 working days to process. Failure to submit the application on time due to late registration will result in ASPR not accepting the application.

2. Content and Form of Application Submission (See section VIII. OTHER INFORMATION)

The following document and sections need to be submitted to ASPR in order to be considered for funding- forms are available on grants.gov:

Application for Federal Assistance – Standard Form SF 424 Budget Information – Standard Form SF 242A Assurances (Non-Construction Programs) - Standard Form SF 424B

Applicants must submit a statement (see attachment E) attesting that funds requested will not be used for costs that are reimbursed by the Federal Emergency Management Agency (FEMA), under a contract for insurance, or by self-insurance. If, during the award, a claim is paid which provides duplication of benefits by FEMA, insurance, or self-insurance (see footnote 1), the grantee will be required to pay back the funds to HHS. If human subjects are involved complete attachment G

Project Narrative

The Project Narrative must be double-spaced, on 8 ½" x 11" paper with 1" margins on both sides, and a font size of not less than 11. You can use smaller font sizes to fill in the Standard Forms and Sample Formats. ASPR will not accept applications with a Project Narrative that exceeds 15 pages. The Monitoring and Evaluation Plan, Curriculum Vitae of Key Personnel and other Annexes are not counted as part of the Project Narrative for purposes of the 15-page limit, but all of the other sections noted below are included in the limit.

The components of the Project Narrative counted as part of the 15 page limit include:

Abstract Goal(s) and Objective(s) Proposed Approach, Work Plan and Timeline of Proposed Activities Overview of Evaluation Plan Organizational Capability

Any Other Relevant Annexes that do not count toward the 15-page limit include:

Grid of detailed M&E Plan Key CV Letters of Commitment Budget Narrative Self-monitoring plan and contingency activities identified to ensure project completion and funding outlays are completed within the 24 month project period Other documents, as needed

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether or not your project meets the minimum requirements for grants under sections 301 of the Public Health Service Act. The Project Narrative should provide a clear and concise description of your project. ASPR recommends that your project narrative include the following components:

Abstract

This section should include a brief (no more than 265 words maximum) description of the proposed project, including: goal(s), objectives, outcomes, and products to be developed. Detailed instructions for completing the abstract are included in Attachment D of this document.

Goal 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. The goal and objectives stated in Section 1 "Funding Opportunity Description" are suggestions and the applicant is free to modify, edit or propose other goal and objectives, but they must similarly align with the ones proposed in this Funding Opportunity Announcement.

** Evaluation Plan**

Applicant should develop an Evaluation plan. The plan should track what outcomes project management is promising to deliver. The evaluation plan should also address how the proposed outcomes could be applied to Sandy response and recovery.

Workplan and Timeline of Proposed Activities

Each proposed grant activity should have clear timelines for execution and completion.

The Project Work Plan should reflect and be consistent with the Project Narrative and Budget and should cover all of the project period. It should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks / action steps that will be pursued to achieve the goal and outcome(s). For each major task / action step, the work plan should identify timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. Please use the Sample Work Plan format included in Attachment C.

Organizational Capability

Each application should include an organizational capability statement. 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/or the capabilities it possesses.

This description should cover capabilities of the applicant agency not included elsewhere in the narrative, such as any current or previous relevant experience and/or the record of the project team in producing cogent and useful reports, publications, or other products.

This section should also include a clear delineation of the roles and responsibilities of project staff, consultants and partner organizations, 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 the project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and ASPR. Curriculum vitae for key project personnel should feature in the annexes.

Other Relevant Annexes

Key Personnel

Please attach short curriculum vitae for key project staff only (no more than one page). Neither curriculum vitae nor an organizational chart will count towards the narrative page limit. Also include information about any contractual organization(s) that will have a significant role(s) in implementing the project and achieving project goals.

Letters of Commitment

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations and agencies in this part of the application. Any organization that is specifically named to have a significant role in

carrying out the project should be considered an essential collaborator. For applications submitted electronically via http://www.grants.gov, signed letters of commitment should be scanned and included as attachments. Applicants unable to scan the signed letters of commitment may email them to asprgrants@hhs.gov or fax them to the ASPR Office of Grants Management at 202-245-0789 by the application submission deadline. In your fax, be sure to include the funding opportunity number and your agency name.

Budget Narrative

The Budget Narrative/Justification should be provided using the format included as Attachment B of this Funding Opportunity Announcement. Applicants are encouraged to pay particular attention to Attachment B, which provides an example of the level of detail sought. A combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding, is required. The Budget Narrative should include travel and relevant expenses to attend the awardee meeting in Washington, DC.

A self-monitoring plan and contingency activities should be identified to ensure project completion and funding outlays are completed within the 24 month project period.

3. Submission Dates and Times

The deadline for the submission of applications under this Funding Opportunity Announcement is May 20, 2013. Applications must be submitted electronically by 9 p.m. Eastern Time on May 20, 2013.

Grants.gov (http://www.grants.gov) will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in http://www.grants.gov. After the Assistant Secretary for Preparedness and Response retrieves your application form from http://www.grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by http://www.grants.gov.

Applications submitted after the due date and time will not be reviewed by ASPR.

Intergovernmental Review

This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

4. Funding Restrictions

The following activities are not fundable:

All salaries are capped at the rate of Executive Level II or 179,900/year USD. Construction is not allowed. To carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. To advocate or promote gun control. Funds cannot be used to lobby. Preaward costs are not allowed.

5. Other Submission Requirements

Complete Applications must be filed at http://www.grants.gov - ASPR will not accept any applications that are not submitted through grants.gov.

V. APPLICATION REVIEW INFORMATION

1. Criteria

Overall Impact

Reviewers will provide an impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review 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. The application will be reviewed using the following criteria. Scores assigned will assist the reviewer in scoring the applications. It is ASPR's practice to fund only those projects that score in the fundable range. Funding decisions will be based on the scored scientific review criteria and the outcome of the secondary review. All funding decisions by ASPR are final.

Applications will be scored using the following criteria:

- 1. Significance/Impact 20 points
- 2. Investigator/organizational capacity- 20 points
- 3. Innovation 20 points
- 4. Approach 20 points
- 5. Evaluation 20 points

Significance/Impact

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? In addition, reviewers will assess:

What is the potential or actual impact of the research for enhancing ongoing recovery activities for Hurricane Sandy? How will the research outcomes provide a practical benefit and have clear application for enhancing recovery in the impacted region and communities?

How will the work be influential in that it will lead others to further investigate the problem, open new areas of research, or change the scientific approach or public health practice?

How will findings strengthen preparedness, response and recovery performance, practice, and policy for future public health emergencies and disasters? How well does the applicant describe the potential for research results to be scalable to other regions of the nation and contribute to the national health security?

Are the proposed outcomes quantifiable and measurable, consistent with the definition of a project outcome contained in Attachment C of the Funding Opportunity Announcement? Is the proposed project justified in terms of the most recent, relevant, and available information and knowledge?

Investigator/Organizational Capacity

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? In addition, reviewers will assess:

Is there evidence of successful past collaborations with the proposed research team and participating organizations? Does the proposed research include collaboration, consultation, or coordination with relevant parties from the regions affected by Hurricane Sandy?

Are the roles and contributions of collaborators and key staff clearly defined including participation in the preparation of the application and the conduct of the proposed research?

Are letters from participating organizations included, as appropriate, and do they express the clear commitment and areas of responsibility of those organizations, consistent with the work plan description of their intended roles and contributions?

Innovation

Discuss how well the application challenges and seeks to shift current research or clinical practice paradigms though the use of 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? In addition, reviewers will assess:

How innovative is the proposed research? Does the innovation offer reasonable potential for concrete applications of interest and value to the ASPR and public health preparedness, response, and recovery?

Approach

Is the project work plan clear and comprehensive? Does it include sensible and feasible timeframes for the accomplishment of tasks presented? Does the work plan include specific objectives and tasks that are linked to measurable outcomes? Does the proposal include a clear and coherent management plan? Does the proposal include a feasible plan for sharing, as applicable, de-identified, documented, and geographically coded data broadly with the research community?

Discuss the extent to which the overall strategy, methodology, and analyses are 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? In addition, reviewers will assess:

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?

Does the proposed research address a priority research area in communities impacted by Hurricane Sandy? How well does the proposed research address the identified priorities for at-risk populations? Will the conduct of the research have minimal or no adverse impact on response and recovery activities, or interfere with critical assistance activities for affected populations and communities?

To what extent does the application propose to use existing tools and/or methodological approaches or evidencebased interventions or strategies from previous studies of public health emergencies or disasters in the research plan?

To what extent does the proposed research incorporate interdisciplinary, mixed methods approaches and teams that are critical to the success of the study?

What is the potential usefulness of the research outputs identified? Does the proposed research include feasible measures/metrics to assess the value of research outcomes?

Does the application describe how results from the research will be disseminated? How well will the dissemination plan make the results readily accessible for use by the public health preparedness and response practice community?

Project Evaluation

Does the project include an evaluation effort to successfully measure whether or not the project has achieved its proposed outcomes? Does the plan include the qualitative and/or quantitative methods necessary to reliably measure outcomes? Is the evaluation also designed to capture "lessons learned" from the overall effort that might be of use to others in the field of preparedness, especially those who might be interested in replicating the project?

2. Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, but will not give separate scores for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under <u>45 CFR Part 46</u>, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation. The committee will assess any IRB materials included in the application, including IRB assessment of standard 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 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

If the proposed research involves the use of human data and/or biological specimens, a justification must be provided for the claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give separate scores for each of these items.

Resource Sharing Plans

Recipients of grant awards should make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Research partnerships or collaborations with organizations in the affected regions and their specific role and contribution to the conduct of the proposed study should be reflected in the proposed budget.

NOTE: Preference will be given to applications submitted by entities that are based or have significant operations in one of the states, including the District of Columbia, identified as a major disaster area (see eligibility criteria).

VI. AWARD ADMINISTRATION INFORMATION

1. Award Notices

The Notice of Award is the authorizing document from the ASPR authorizing official, the Officer of Grants Management, and the ASPR Office of Financial Planning and Analysis. The Notice of Award will be sent electronically upon successful review of the application. The Notice of Award sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-federal share to be provided (if applicable), and the total project period for which support is contemplated.

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to

Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

2. Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 45CFR Part 74 and 92 and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement located at http://www.hhs.gov/grantsnet/adminis/gpd/index.htm.

The signature of the authorized organizational representative on the application indicates that the organization complies, or intends to comply, with all applicable public policy requirements as listed in Attachment F of this document.

3. Reporting

Applicants funded under this announcement will be required to electronically submit quarterly program progress reports and Federal Financial Reports (FFR) SF-425. Final performance and financial reports are due 90 days after the end of the project period.

Progress Reporting: Applicants funded under this announcement will be required to electronically submit quarterly program progress reports. As part of the progress report, financial information will be reported both per major category of expense, and by objectives. Grantees will include sub-recipient monitoring activities that were completed during each quarter.

Subaward and Executive Compensation Reporting: Applicants must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements established under OMB guidance at <u>2 CFR Part 170</u>, unless they qualify for an exception from the requirements, should they be selected for funding.

Cash Transaction Reporting: Recipients must report cash transaction data using the Federal Financial Report (FFR), SF-425. Recipients will utilize the SF-425 lines 10.a through 10.c to report cash transaction data to the Division of Payment Management. The FFR SF-425 (lines 10.a through 10.c) is due to the Payment Management System 30 days after the end of each calendar quarter. The FFR SF-425 electronic submission and dates for the new quarters will be announced through the Payment Management/SmartLink Payment System's bulletin board. Funds will be frozen if the report is not filed on or before the due date.

Federal Disbursement Reporting: The SF-425 will also be used for reporting of expenditure data to meet ASPR's quarterly financial reporting requirement. All other lines except 10.a through 10.c should be completed.

Tangible Property Report: Awardees will be required to submit an annual (after each 12 month period) Tangible Property Report (SF 428). Final SF 428 reports are due 90 days after the end of the project period.

<u>Annual A-133 Audits:</u> In accordance with the provisions of OMB Circular No. A-133 (Revised, June 27, 2003), "Audits of States, Local Governments, and Non-Profit Organizations," nonfederal entities that expend financial assistance of \$500,000 or more in Federal assistance awards will have a single or a program-specific audit conducted for that year. Nonfederal entities that expend less than \$500,000 a year in Federal awards are exempt from Federal audit requirements for that year, except as noted in Circular No. A-133. Grantees will be required to audit this program as a major program.

ASPR will closely monitor all grants and, throughout the course of the project, the grantee may be asked to submit additional reports and other documents.

ASPR will conduct a financial and management capability review. Applicants/grantees will be asked to provide financial and management documents to allow ASPR to complete this requirement.

VII. AGENCY CONTACTS

Grants Management Officer:

U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response Washington, DC 20201 Attn: Barbara Orlando Telephone: (202) 245-0961, e-mail: <u>asprgrants@hhs.gov</u>

Project Officer:

U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response Washington, DC 20201 Attn: Jessica Tucker

Telephone: (202)260-0632

e-mail: <u>Jessica.tucker@hhs.gov</u>

VIII. OTHER INFORMATION

Review and Selection Process

There are two phases in the application review process. The initial step is the scientific and technical merit review using the criteria listed in Section V.1. Applications will be assigned to an internal Federal panel to conduct the scientific review, and all applications will receive written comments and a scientific and technical merit score.

A secondary review will be conducted for those applications deemed to have the highest scientific and technical merit scores (generally the top 50% of applications under review). In the secondary review, those top-scoring applications will be discussed in the context of the criteria described below, which will inform funding decisions. In the second level review, applications submitted under this FOA (*EP-HIT-13-001*) and a similar CDC FOA (*TP13-001*) will be reviewed together to avoid redundancy and maximize the impact of Federal funding dollars for this research.

The following will be considered in making funding decisions, in this order:

Scientific and technical merit of the proposed project as determined by scientific review.
Preference for applications submitted by entities that are based or have significant operations in one of the states, including the District of Columbia, identified as a major disaster area (see eligibility criteria).
Applications with research in HHS priority areas that are overlapping between the two FOAs #(EP-HIT-13-001 and TP13-001) for ASPR and CDC, respectively, will be considered based upon the following factors:

- The avoidance of funding unnecessary redundant research between the two FOAs.
- Funding those meritorious applications that best address research in the overlapping HHS priority areas between the two FOAs.

The following will also be considered in making funding decisions, in no particular order:

Existence of research collaboration or partnership with agencies/organizations/entities, as defined in the respective FOAs, from regions directly affected by Hurricane Sandy.

Consideration of funding research across all of the identified HHS priority areas.

Availability of funds.

Application Elements

a. SF 424 - Application for Federal Assistance (See Attachment A for Instructions).

b. SF 424A - Budget Information. (See Attachment A for Instructions).

c. Separate Budget Narrative/Justification (See Attachment B for a Budget Narrative/Justification Sample Format with Examples and a Sample Template).

NOTE: Applicants requesting funding for multi-year grant projects are REQUIRED to provide a combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding.

d. SF 424B – Assurances. Note: Be sure to complete this form according to instructions and have it signed and dated by the authorized representative. Applicants must download the assurances, then sign and upload into grants.gov.

Failure to submit the signed assurances may result, if otherwise eligible, in not receiving an award.

e. Lobbying Certification.

f. Proof of non-profit status, if applicable.

g. Copy of the applicant's most recent indirect cost agreement, if requesting indirect costs. Upon issuing a contract or sub-award, copies of their indirect cost agreements must be forwarded to the Division of Grants.

h. Project Narrative with Work Plan (See Attachment C for Sample Work Plan Format).

i. Organizational Capability Statement and Vitae for Key Project Personnel.

j. Letters of Commitment from Key Partners.

k. Insurance Agreement (Attachment E)

4. The Paperwork Reduction Act of 1995 (P.L. 104-13)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The project description and Budget Narrative/Justification is approved under OMB control number 0985-0018 which expires on 5/31/10. Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

ATTACHMENTS

Attachment A: Instructions for Completing Required Forms (SF 424, Budget (SF 424A), Budget Narrative/Justification)

Attachment B: Budget Narrative/Justification Format – Sample Format with Examples

> Attachment C: Project Work Plan - Sample Template

Attachment D: Instructions for Completing the Summary/Abstract

Attachment E: Insurance Statement

Attachment F: Potentially Applicable Public Policy Requirements

Attachment A: Instructions for Completing Required Forms (SF 424, Budget (SF 424A), Budget Narrative/Justification)

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. ASPR does not require all the information on these Standard Forms. Accordingly, please use the instructions below in lieu of the standard instructions attached to SF 424 and 424A to complete these forms.

a. Standard Form 424

- 1. Type of Submission: (Required): Application
- 2. **Type of Application**: (Required) New
- 3. Date Received: Leave this field blank.
- 4. **Applicant Identifier**: Leave this field blank
- 5a Federal Entity Identifier: Leave this field blank
- 5b. Federal Award Identifier: Leave this field blank
- 6. Date Received by State: Leave this field blank.
- 7. State Application Identifier: Leave this field blank.
- 8. **Applicant Information**: Enter the following in accordance with agency instructions:
 - **a.** Legal Name: (Required): Enter the name that the organization has registered with the Central Contractor Registry.

b. Employer/Taxpayer Number (EIN/TIN): (Required): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service.

c. Organizational DUNS: (Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet.

d. Address: (Required) Enter the complete address including the county.

e. Organizational Unit: Enter the name of the primary organizational unit (and department or division, if applicable) that will undertake the project.

f. Name and contact information of person to be contacted on matters involving this application: Complete

9. **Type of Applicant:** (Required) Select the applicant organization "type" from the drop down list.

10. Name of Federal Agency: (Required) Enter U.S. Assistant Secretary for Preparedness and Response

11. Catalog Of Federal Domestic Assistance Number/Title: 93.095

12. Funding Opportunity Number/Title: (Required) EP-HIT-13-001

13. **Competition Identification Number/Title:** Leave this field blank.

14. Areas Affected By Project: List the largest political entity affected (cities, counties, state etc).

15. **Descriptive Title of Applicant's Project:** (Required) Enter a brief descriptive title of the project.

16. **Congressional Districts Of**: (Required) **16a**. Enter the applicant's Congressional District, and **16b**. Enter all district(s) affected by the program or project. Enter in the format: 2 characters State Abbreviation – 3 characters District Number, e.g., CA-005 for California 5th district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all.

17. Proposed Project Start and End Dates: (Required) Aug. 15, 2013 through Aug. 14, 2015

18. Estimated Funding: (Required) Enter the amount requested.

19. Is Application Subject to Review by State Under Executive Order 12372 Process? Check appropriate box

20. **Is the Applicant Delinquent on any Federal Debt?** (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

21. **Authorized Representative**: (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required) title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

b. Standard Form 424A

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this ASPR program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a one year budget.

Section A - Budget Summary

Line 5: Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total non-Federal costs (including third party in-kind contributions and any program income to be used as part of the Awardee match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B - Budget Categories

Column 3: Enter the breakdown of how you plan to use the Federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-Federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.

Line 6a: **Personnel**: Enter total costs of salaries and wages of applicant/Awardee staff. Do not include the costs of consultants, which should be included under 6h - Other.

Line 6b: **Fringe Benefits**: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate.

Line 6c: **Travel**: Enter total costs of all travel (local and non-local) for staff on the project. NEW: Local travel is considered under this cost item not under Other.

Local transportation (all travel which does not require per diem is considered local travel). Do not enter costs for consultant's travel - this should be included in line 6h.

Line 6d: **Equipment**: Enter the total costs of all equipment to be acquired by the project. For all Awardees, "equipment" is non-expendable tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more *per unit*. If the item does not meet the \$5,000 threshold, include it in your budget under Supplies, line 6e.

Line 6e: **Supplies**: Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d.

Line 6f: **Contractual**: Regardless of the dollar value of any contract, you must follow your established policies and procedures for procurements and meet the minimum standards established in the Code of Federal Regulations (CFR's) mentioned below. Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.). Note: The 33% provision has been removed and line item budget detail is not required as long as you meet the established procurement standards. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line.

Line 6g: **Construction**: Leave blank since construction is not an allowable costs for this program.

Line 6h: **Other**: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits),non-contractual fees and travel paid directly to *individual* consultants, postage, space and equipment rentals/lease, printing and publication, computer use, training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs.

Line 6i: **Total Direct Charges**: Show the totals of Lines 6a through 6h.

Line 6j: **Indirect Charges**: Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. **State governments should enter the amount of indirect costs determined in accordance with DHHS requirements.** An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. Indirect Costs can only be claimed on Federal funds, more specifically, they are to only be claimed on the Federal share of your direct costs.

Awardee's eligible Indirect Cost amount that are not claimed on the Federal share of direct charges can be claimed as un-reimbursed indirect charges, and that portion can be used towards meeting the recipient match.

NOTE:. If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-Awardees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

Line 6k: Total: Enter the total amounts of Lines 6i and 6j.

Line 7: **Program Income**: As appropriate, include the estimated amount of income, if any, you expect to be generated from this project that you wish to designate as match (equal to the amount shown for Item 15(f) on Form 424). **Note:** Any program income indicated at the bottom of Section B and for item 15(f) on the face sheet of Form 424 will be included as part of non-Federal match and will be subject to the rules for documenting completion of this pledge. If program income is expected, but is not needed to achieve matching funds, **do not** include that portion here or on Item 15(f) of the Form 424 face sheet. Any anticipated program income that will not be applied as Awardee match should be described in the Level of Effort section of the Program Narrative.

Section C - Non-Federal Resources

Line 12: Enter the amounts of non-Federal resources that will be used in carrying out the proposed project, by source (Applicant; State; Other) and enter the total amount in Column (e). Keep in mind that if the match requirement is not met, Federal dollars may be reduced.

Section D - Forecasted Cash Needs - Not applicable.

Section E - Budget Estimate of Federal Funds Needed for Balance of the Project

Line 20: Section E is relevant for multi-year grant applications, where the project period is 24 months or longer. This section does not apply to grant awards where the project period is less than 17 months.

Section F - Other Budget Information

Line 22: Indirect Charges: Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

Line 23: Remarks: Provide any other comments deemed necessary.

c. Standard Form 424B - Assurances

This form contains assurances required of applicants under the discretionary funds programs administered by the Assistant Secretary for Preparedness and Response. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. Certification Regarding Lobbying

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

Proof of Non-Profit Status

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

A copy of a currently valid IRS tax exemption certificate.

- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency. This is optional for applicants that have not included indirect costs in their budgets.

Attachment B: Budget Narrative/Justification - Page 1 - Sample Format

The Budget Summary is used to determine reasonableness and allowability of costs for the project. All of the proposed costs listed, whether supported by Federal funds or non-Federal match, must be reasonable, necessary to accomplish project objectives, allowable in accordance with applicable Federal cost principles, auditable, and incurred during the budget period.

Non-Federal Match: (include when grant requires the match/cost sharing)

Matching funds provide support for the purpose and goals of this proposal and enhance the Federal budget request. Applicant is required to provide a detailed listing of all match used to meet the match requirement. In the narrative justification sections describe how the funds support the project and enhance the Federal budget.

All funding used for match must be documented in the same manner as Federal funds. All match funds must follow the same cost principles and regulations that are used for Federal funds – to count as match you must be able to use Federal funds to purchase the item.

An allowable project cost is a cost that is:

- Necessary for the performance of the award. Allocable to the project.
- In conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost.
- Consistent with the recipient's regulations, policies, and procedures which are applied uniformly to both Federally-supported and other activities of the organization.
 - Accorded consistent treatment as a direct or indirect cost.
 - Determined in accordance with generally accepted accounting principles.
 - Not included as a cost in any other Federally-supported award.

The following four tests are used in determining the allowability of costs:

• **Reasonableness (including necessity)**. A cost is reasonable if it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large, as well as to their organization.

- Allocability. A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable if it is incurred solely to advance work under the grant; it benefits both the grant and other work of the organization, including other grant-supported projects or programs; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant.
- **Consistency.** Recipients must be consistent in assigning costs to cost objectives. Regulations regarding cost assignment must be consistent for all work of the organization under similar circumstances, regardless of the source of funding, to avoid duplicate charges.
- **Conformance.** Conformance with limitations and exclusions contained in the Terms and Conditions of award, including those in the cost principles, may vary by the type of activity, the type of recipient, and other characteristics of individual awards.

Budget Summary (only include section for Non-Federal Match if required by the application)

Section A: Personnel - An employee of the applying agency whose work is tied to the application. Proposed salaries must be reasonable. Compensation paid for employees must be reasonable and consistent with that paid for similar work within the applicant's organization and similar positions in the industry.

Non-Federal Match: Separately list all personnel that will be working on the project and whose time and effort will be used to meet the non-Federal Match requirement. Personnel used as match must be documented through signed time cards and payroll documents. List the source of the match – i.e. State funds.

Position	Name	Annual	Level of	Federal	Match
		Salary/Rate	Effort	Cost	
Project	Susan Jones	\$45,000/year	100%	\$45,000	
Director					
Project	Brad Smith	\$42,000/year	50%	\$21,000	
Coordinator					
			TOTAL	\$66,000	

Table 1: Personnel

TOTAL\$66,000NARRATIVE JUSTIFICAITON:Enter a description of the personnel funds requested and how their use willsupport the purpose and goals of this proposal.Describe the role, responsibilities, and unique qualifications ofeach position.

B. Fringe Benefits: Fringe benefits may include contributions for items such as social security, employee insurance, and pension plans. Only those benefits not included in an organization's indirect cost pool may be shown as direct costs. If fringe benefits are not computed as a percentage of salary (i.e. 25%), list all components of the fringe benefits rate, for example:

Non-Federal Match: List for all personnel shown in table 1 under the match section. Match documentation includes payroll records and pay slips. List the source of the match – i.e. State funds.

Table 2: Fringe Benefits

Component	Rate	Wage	Federal	Match
			Cost	
FICA	7.65%	66,000	\$5,049	
Insurance	5%	66,000	\$3,300	
		TOTAL	\$8,349	

NARRATIVE JUSTIFICATION: Enter a description of the fringe funds requested and how the rate was determined.

<u>C. Travel</u>: Federal funds requested for travel are for staff travel only (travel for consultants is listed in consultant category). Travel for other participants, committee members, etc. should be listed under the cost category "other". Applicants are to use the lowest available commercial fares for coach or equivalent accommodations. Note that Applicants will be expected to follow Federal travel policies found at http://www.gsa.gov. Non-Federal Match: The travel costs must be documented through travel authorizations and paid vouchers. Local travel should be documented by miles traveled. List the source of the match – i.e. State funds.

Table 3: Travel

Purpose of Travel	Location	Item	Rate	Federal Cost	Match
Attend awardee	Washington, DC	Air Fare	\$350 X 4 people	\$1,400	
meeting		Per Diem	\$71/day X 4 days X		
			4 people	\$1,136	
		Airport	\$10/day X 4 days	\$40	
		Parking	\$28/RT X 4 people	\$112	
		Airport	\$211/night X 3		
		Shuttle	nights X 4 people	\$2532	
		Hotel	Subtotal	\$4,120	
Local travel	Various	POV	.44/mile X 2,000	\$880	
			miles/year		
			TOTAL	\$5,000	

NARRATIVE JUSTIFICATION: Explain the purpose for all travel and how costs were determined. List any required travel, funds for local travel that are needed to attend local meetings, project activities, and training events. Local travel rate should be based on agency's personally owned vehicle (POV) reimbursement rate, which should correspond with the GSA rate found at <u>http://www.gsa.gov</u>.

D. Equipment: Permanent equipment is defined as tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more. If the applying agency defines "equipment" at a different rate, then follow the applying agency's policy. In the case of vehicles, etc. applicant should justify purchase rather than rental. If equipment is used by several different projects, you may only charge a percentage of the costs for the purchase based on the amount of time, etc. that the equipment will be used for this grant program. Any purchased equipments must be inventoried according to the guidelines in the HHS Grants Policy Statement.

Non-Federal Match: Enter a description of the equipment match provided and how its use will support the purpose and goals of this proposal. Documentation of match should be in inventory and use records. List the source of the match – i.e. State funds.

Table 4: Equipment

Item(s)	Rate	Federal	Match
		Cost	
Computer Work Station	\$5,500 X 2	\$11,000	
Computer	\$6,000 X .5FTE	\$3,000	
	TOTAL	\$ 14,000	

NARRATIVE JUSTIFICATION: Enter a description of the equipment and how its purchase will support the purpose and goals of this proposal.

<u>E. Supplies</u>: Materials costing less than \$5,000 per unit and often having one-time use, for example – general office supplies, postage, printers, etc.

Non-Federal Match: Please note that items such as computers, desks, and projection equipment may be counted as match only once throughout the life of the project. Documentation includes invoices and donation records. List the source of the match – i.e. State funds.

Table 5: Supplies

Item(s)	Rate	Federal Cost	Match
General Office Supplies	\$50/month X 4 FTE	\$200	
	TOTAL	\$200	

NARRATIVE JUSTIFICATION: Enter a description of the supplies requested and how their purchase will support the purpose and goals of this proposal. Rates for office supplies, etc. may be based on average monthly costs, FTE, etc.

F. Contracts and Consultants: An arrangement to carry out a portion of the programmatic effort by a third-party or for the acquisition of goods or services is allowed under the grant. Such arrangements may be in the form of sub awards (grants) or contracts. A consultant is a non-employee retained to provide advice and expertise in a specific program area for a fee. List each contract, consultant or sub award separately and provide an itemization of the costs. If a contractor is to be determined, provide a best estimate as to costs for the goods or services to be purchased.

The awardee must establish written procurement policies and procedures that are consistently applied. All procurement transactions are required to be conducted in a manner to provide to the maximum extent practical, open and free competition. The awardee should be alert to organizational conflicts of interest as well as to noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

Method of Selection: This will be sole source, competition, or grant.

Scope of Work: Provide a breakout of the goods and/or services being provided by the contractor. If personnel are being charged then should list name, position, hours and rate/hour. Goods will be listed at number of units

and cost/unit. List method to be used for sub-recipient monitoring – site visit, semi-annual reports, etc. Documentation of monitoring should be kept with the contract/award file.

Non-Federal Match: Enter any contracts, etc. that are being used to meet this requirement. When making a contract, a portion may be "donated" to this project by the contracted organizations and should be so noted in the contractual agreement (i.e.: Media outlets may give one free ad for each purchased). If this arrangement has been reached, it should be noted in the justification section. Documentation includes copies of contractual agreements, payment and donation records.

Table 6: Contract/Sub award

Activity	Name	Method of	Scope of Work	Federal	Match
		Selection		Cost	
Public	WMTV	Sole source	Paid Ads 12/month X	\$18,000	
Information			\$250/ad X 6 mo.		
			Paid Ads 12/month X		\$18,000
			\$250/ad X 6 mo		
			Monitoring: semi-annual		
			report		
Mobil	То Ве	Competition	Medical supply inventory	\$223,600	
Medical	Determined		(\$1,600)		
Assets			Wheelchair bus		
			conversions(6 X \$37,000)		
			Monitoring: semi-annual		
			report		
			TOTAL	\$ 241,600	\$18,000

NARRATIVE JUSTIFICATION: Provide information as to how the contracted services or goods will enhance the project goals and objectives. Provide sole source justification.

Table 7: Consultant

Organization Name		Name Number of Rates		Federal	Match
		Days		Cost	
Trepid	Jon Smith	20	\$150/day	\$ 7,816	
			Travel 4 trips X 1,204		
			(travel @ \$475; lodging @		
			\$175/night X 3; Per Diem		
			@ \$51 x4) = \$4,816		
			TOTAL	\$ 7,816	

NARRATIVE JUSTIFICATION: Provide information as to how the consultant services or goods will enhance the project goals and objectives.

<u>G. Other:</u>

Expenses not covered in any of the previous budget categories. If rent is requested (direct or indirect), provide the name of the owner(s) of the space/facility. If anyone related to the project owns the building which is less than an arm's length arrangement, provide cost of ownership/use allowance calculations.

Non-Federal Match: Break down costs into cost/unit (e.g., cost/square foot) and explain the use of each item requested. Documentation includes donation, usage, transaction and/or payment records. List the source of match funds – i.e. State funds.

Table 8: Other

Item	Rate	Federal Cost	Match
Postage	\$65/mo. X 4 FTE	\$3,120	
	TOTAL	\$3,120	

NARRATIVE JUSTIFICATION: Explain the need for each item and how it will support the purpose and goals of this proposal. Break down costs into cost/unit (e.g., cost/square foot or cost/month or cost/FTE).

H. Indirect Costs:

Also known as "facilities and administrative costs", indirect costs are costs that cannot be specifically identified with a particular project, program, or activity, but are necessary to the operation of the organization (i.e., overhead). Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that are usually treated as indirect costs. The organization must not include costs associated with its indirect rate as direct costs. If indirect costs are claimed, applicant is to submit a copy of a current negotiated indirect cost rate agreement. Indirect costs are only charged on the items cited in the indirect cost rate agreement (i.e. – personnel and fringe, subawards over \$25,000).

Non-Federal Match: Unclaimed indirect costs for costs incurred by using the Federal funds may be used to meet the match requirement. Indirect costs may be charged on the appropriate costs listed in the match categories that are provided by the applicant agency. Documentation should be included in the accounting records of the applicant agency.

Table 9: Indirect costs

Total Direct Cost applied to Indirect Cost	Indirect Cost Rate	Federal Cost	Match
\$450,000	22%	\$99,000	
	TOTAL	\$99,000	

I. FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Table 10: FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Provide a summary of the year one proposed costs (both direct and indirect). Provide the best estimate of the funding that will be needed for each of the years to complete the total project period (for HPP 4 years).

* FUNDING REQUESTED FOR YEARS 2 THROUGH 4

1. Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.

2. If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policies and procedures that state all employees within the organization will receive a COLA.

Attachment C: Project Work Plan, Page 1 – Sample Template

Goal: Measurable Outcome(s):

Major Objectives	Key Tasks	Load Borcon	Lead Person 1* 2* 3			Start/End Dates by Month in Proj								10*11*12		
Major Objectives	Key Tasks	Leau Fei soli	1.	2	3	4	5	0	/	0	9	10.	11.	12		
1.																
														-		

Add as many pages as needed

Attachment D: Instructions for Completing the Project Summary/Abstract

All applications for grant funding must include a Summary/Abstract that concisely describes the proposed project. It should be written for the general public.

To ensure uniformity, please limit the length to no more than 265 words on a single page with a font size of not less than 11, doubled-spaced.

The abstract must include the project's goal(s), objectives, overall approach (including target population and significant partnerships), anticipated outcomes, products, and duration. The following are very simple descriptions of these terms, and a sample Compendium abstract.

Goal(s) – broad, overall purpose, usually in a mission statement, i.e. what you want to do, where you want to be

Objective(s) – narrow, more specific, identifiable or measurable steps toward a goal. Part of the planning process or sequence (the "how"). Specific performances which will result in the attainment of a goal.

Outcomes - measurable results of a project. Positive benefits or negative changes, or measurable characteristics that occur as a result of an organization's or program's activities. (outcomes are the end-point)

Products – materials, deliverables.

A model abstract/summary is provided below:

The Awardee, Okoboji University, supports this three year Dementia Disease demonstration (DD) project in collaboration with the local Alzheimer's Association and related Dementias groups. The **goal** of the project is to provide comprehensive, coordinated care to individuals with memory concerns and to their caregivers. The approach is to expand the services and to integrate the bio-psycho-social aspects of care. The **objectives** are: 1) to provide dementia specific care, i.e., care management fully integrated into the services provided; 2) to train staff, students and volunteers; 3) to establish a system infrastructure to support services to individuals with early stage dementia and to their caregivers; 4) to develop linkages with community agencies; 5) to expand the assessment and intervention services; 6) to evaluate the impact of the added services; 7) to disseminate project information. The expected **outcomes** of this DD project are: patients will maintain as high a level of mental function and physical functions (thru Yoga) as possible; caregivers will increase ability to cope with changes; and pre and post – project patient evaluation will reflect positive results from expanded and integrated services. The **products** from this project are: a final report, including evaluation results; a website; articles for publication; data on driver assessment and in-home cognitive retraining; abstracts for national conferences.

Attachment E: Insurance Statement

I attest that funds requested will not be used for costs that are reimbursed by the Federal Emergency Management Agency (FEMA), under a contract for insurance, or by self-insurance. If, during the award, a claim is paid which provides duplication of benefits by FEMA, insurance, or self-insurance*, the grantee will be required to pay back the funds to HHS.

Name of authorized representative:

Signature of authorized representative

Date

*Note - Self-insurance is a formal plan, pursuant to law or regulation, in which amount are set aside in a fund to cover losses of specified types and amounts, typically by a commercial insurance company. Appropriated funds are precluded from expenses that are or can be reimbursed by the formal selfinsurance plan Attachment F

II. Potentially Applicable Public Policy Requirements

The following table specifies those public policy requirements that may apply to all or a subset of HHS grant programs and awards. The following key applies to use of this table. The "Types of Applicants/Recipients" column indicates applicability by type of entity, the "Types of Subrecipients" and "Contractors under grant" columns indicate whether the requirement flows down, as well as applicability by organizational type. An "NA" means it does not flow-down.

es or Encouragemer	nts		
Applicability	Types of Applicants/ Recipients	Subawards	Contracts for routine goods/services
All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
Applications and awards for activities involving warm- blooded animals	All	All	All
All awards	All	All	All
Research awards (includes research training in each case specified as "research")	All	All	All
All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
All research awards and awards to substance abuse programs	All	All	All
All covered applications and awards	All	NA	NA
	Applicability All applications from and awards to domestic entities Applications and awards for activities involving warm- blooded animals All awards All awards Research awards (includes research training in each case specified as "research") All applications from and awards to domestic entities All research awards and awards to substance abuse programs All covered applications and	ApplicabilityTypes of Applicants/ RecipientsAll applications from and awards to domestic entitiesNA to foreign and international organizationsApplications and awards for activities involving warm- blooded animalsAllAll awardsAllAll awardsAllResearch awards (includes research training in each case specified as "research")AllAll applications from and awards to domestic entitiesAllAll applications from and awards to domestic entitiesAllAll research awards and awards to substance abuse programsAllAll covered applications andAll	ApplicabilityTypes of Applicants/ RecipientsSubawardsAll applications from and awards to domestic entitiesNA to foreign and international organizationsNA to foreign and international organizationsApplications and awards for activities involving warm- blooded animalsAllAllAll awardsAllAllAll applications from and awards to domestic entitiesNA to foreign and international organizationsAll research awards and awards to substance abuse programsAllAll covered applications andAllAll covered applications andAll

Education Amendments of 1972 (Title IX)	All applications from and awards to domestic entities	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations
Financial Conflict of Interest	All applications and awards for research	Does not apply to Phase I of the SBIR/STTR programs and to Federal institutions	All except Federal institutions	NA
Fly America Act/ U.S. Flag Air Carriers	All types of awards	All	All	All
Hatch Act	Awards to State or local governments	All	All	NA
Health Insurance Portability and Accountability Act (HIPAA)	All awards to covered entities	All covered entities	All covered entities	All covered entities
Historic Preservation/ Archaeological Sites	All awards that include major or minor A&R, construction, or any work that will result in physical changes to real property	All	All (Note: applicability to subrecipients is being considered based on recent litigation)	All
Human Subjects Protections	Research applications and awards	All	All	All
Investigational New Drug Applications/ Investigational Device Exceptions	Research awards	All	All	All
Limited English Proficiency	All types of awards	All	All	NA
Lobbying	Varies depending on source of requirement Byrd Anti-Lobbying Amendment applies to all awards expected to exceed \$100,000 (except that Indian tribes, tribal organizations,	All consistent with "Applicability"	All consistent with "Applicability"	All consistent with "Applicability"

	and any other Indian organizations may be exempted from the Byrd Anti- Lobbying Amendment with respect to expenditures specifically permitted by other federal law) Cost principles apply as indicated therein Limitations in 18 U.S.C. 1913 apply to all awards			
Military Recruiting and Reserve Officer Training Corps Access	All types of applications and awards	Institutions of higher education	Institutions of higher education	NA
Pro-Children Act	All awards performed in facilities where children are served	All	All	All
Protection of Research Subjects' Identity	All research awards	All	All	All
Public Health Security and Bioterrorism Preparedness and Response Act	All types of awards	All	All	All
Recombinant DNA Molecules and Human Gene Transfer Research	Applications and awards for research	All	All	All
Research Misconduct	Applications and awards for research and research training	All	NA	NA
Research on Transplantation of Human Fetal Tissue	Research awards	All	All	All

Resource Conservation and Recovery Act	All awards to States or agency of a political subdivision of a State (which for this purpose includes State and local institutions of higher education or hospitals)	All	All	All
Seat Belt Use (EO 13043)	All types of awards	All	NA	NA
Smoke-Free Workplace	All awards	All	NA	NA
Standards of Conduct	All types of awards	All	NA	NA
Text Messaging While Driving (EO 13513)	All			
Trafficking in Persons (Trafficking Victims Protection Act, as amended; 2 CFR part 175	All types of awards	Private entities	Private entities	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act	All awards, but, in particular, those involving acquisition of real property	All	All	NA
USA PATRIOT Act	All types of awards	All	All	All

Attachment G :Research and Related Project Information - Provide the following information to the related questions

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no.

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with policies covering human subjects research.

1. Are Human Subjects Involved? YES NO

1.a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? YES NO

Yes: If the project is exempt from Federal regulations, check Yes.

No: If the project is not exempt from Federal regulations, check No.

If yes, Select the appropriate exemption number from 1, 2, 3, 4, 5, 6.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHPR guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (<u>http://answers.hhs.gov/ohrp/categories/1564</u>). Institutions often designate their IRB to make this determination. Since IRB approval is not required at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. Human subjects research should be designated as exempt if the proposed research meets the criteria for one or more of the six exemptions.

If no, is the IRB review Pending? **YES**

NO

Enter the latest Institutional Review Board (IRB) approval date. Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle. If IRB is still pending at time of award then affected components of the award will be restricted. Failure to obtain IRB approval within the agreed upon time frame may result in the termination of an award.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 21 on the SF424 declaring that it will comply with 45 CFR part 46 and proceed to obtain a human subjects assurances (see http://www.hhs.gov/ohrp). Do not insert the human subjects assurance number of any collaborating institution in the space provided.

2. Are Vertebrate Animals Used? YES

NO

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

2.a. If YES to Vertebrate Animals

Is the Institutional Animal Care and Use Committee (IACUC) review Pending?

YES NO

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending.

Animal Welfare Assurance Number:

Enter the Federally approved assurance number, if available.

To determine if your organization holds an Animal Welfare Assurance, see

http://grants.nih.gov/grants/olaw/olaw.htm#assur. Applicants should check "Yes" to the question "Is the IACUC review Pending?" even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle. If the applicant organization does not have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), NIH, enter "None" in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW. If IACC approval is still pending at time of award then affected components of the award will be restricted. Failure to obtain IACC approval within the agreed upon time frame may result in the termination of an award.

3. Is proprietary/privileged information included in the application? YES NO

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation. "

4. Environmental Questions

Most research grants are not expected to individually or cumulatively have a significant effect on the environment, and there are several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the line marked "Yes" should be checked and an explanation provided in field 4.b.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.

- 2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
- 3. Potential effects of the proposed research are unique or highly uncertain.
- 4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
- 5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
- 6. The proposed research may have a possible impact on endangered or threatened species.
- 7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
- 8. The proposed research may introduce new sources of radiation or radioactive materials.
- 9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does this project have an actual or potential impact on the environment?

YES NO

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed? YES NO

4.d. If yes, please explain

Enter additional details about the EA or EIS. If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments** located to the right of Step 11 - Other Attachments.

5. Is the research performance site designated, or eligible to be designated, as a historic place? YES NO

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes and then provide an explanation. Otherwise, check the No.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators? YES NO

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no..

Applicants to PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.