



Centers for Disease Control and Prevention

National Center for Environmental Health Extramural Research Program Office

Environmental Health Specialists Network (EHS-Net) - Practice based research to improve food safety

RFA-EH-15-001

Application Due Date: 04/10/2015

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Environmental Health Extramural Research Program Office (NCEH ERPO)

National Center for Environmental Health (NCEH)

Funding Opportunity Announcement (FOA) Title

Environmental Health Specialists Network (EHS-Net) - Practice based research to improve food safety

Activity Code

Applications in response to this FOA will be funded using the U01 activity code.

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-EH-15-001

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.070

Category of Funding Activity:

Health

FOA Purpose

The Environmental Health Specialists Network (EHS-Net) is a collaborative forum of environmental health specialists who work together to improve environmental health practice. EHS-Net seeks to improve the practice of environmental health service programs by developing and sustaining a network of environmental health specialists (EHS) who collaborate with epidemiologists, laboratorians and other public health professionals to conduct practice-based research to identify and prevent environmental risk factors contributing to foodborne illness. For information on EHS-Net activities, please visit <http://www.cdc.gov/nceh/ehs/EHSNet/index.htm>.

This announcement will fund EHS-Net-related research projects for food safety activities under the jurisdiction of departments of health or other agencies responsible for regulatory oversight of retail food service including restaurants, delis, cafeterias, schools, etc.

The purpose of this FOA is to provide additional clarifying information based on questions received from potential applicants during the Pre-Application Conference Call or as a result of direct communication with the Scientific Program Official. A summary of the "questions and answers" and a list of changes made to the original FOA begins on page 32.

Key Dates

Publication Date: To receive notification of any changes to RFA-EH-15-001, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date: 03/12/2015

Application Due Date: 04/10/2015

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: 07/01/2015

An approximate date; however, the review will be conducted in July, 2015

Secondary Review: 07/22/2015

An approximate date; however, the review will be conducted between July and August, 2015

Estimated Start Date: 09/30/2015

An approximate date; however, the start date is planned for September 2015

Expiration Date: 04/11/2015

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

The Research Strategy component of the Research Plan is limited to 25 pages.

Executive Summary

Purpose. The Environmental Health Specialists Network (EHS-Net) is a collaborative forum of environmental health specialists who work together to improve environmental health practice. EHS-Net seeks to improve the practice of environmental health service programs by developing and sustaining a network of environmental health specialists (EHS) who collaborate with epidemiologists, laboratorians and other public health professionals to conduct practice-based research to identify and prevent environmental risk factors contributing to foodborne illness. For information on EHS-Net activities, please visit <http://www.cdc.gov/nceh/ehs/EHSNet/index.htm>.

This announcement will fund EHS-Net-related research projects for food safety activities under the jurisdiction of departments of health or other agencies responsible for regulatory oversight of retail food service including restaurants, delis, cafeterias, schools, etc.

The purpose of this FOA is to provide additional clarifying information based on questions received from potential applicants during the Pre-Application Conference Call or as a result of direct communication with the Scientific Program Official. A summary of the "questions and answers" and a list of changes made to the original FOA begins on page 32.

Mechanism of Support. Cooperative agreement; an assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Funds Available and Anticipated Number of Awards. NCEH intends to commit approximately \$1,425,000 in FY 2015 to fund up to eight applications. The maximum amount per award for the first 12-month budget period is \$178,125 (direct and indirect costs). Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received and approved.

Budget and Project Period. The estimated total funding (direct and indirect costs) for the first 12-month budget period is expected to be \$1,425,000 (direct and indirect costs) and the estimated total funding for the entire project period is expected to be \$7,125,000 (direct and indirect costs). The project period will run from 09/30/2015 to 09/29/2020.

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in [Section IV. Application and Submission Information](#) of this announcement.

Eligible Institutions/Organizations. Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

Number of PDs/PIs Co-principal investigators are allowed for this FOA; their names must appear on the face page of the application. However, one principal investigator must be designated as the contact PI. For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

Number of Applications. Eligible applicant institutions may submit more than one application, provided that each application is scientifically distinct. However, applicant institutions can submit only one grant application with the same principal investigator. Only one application per principal investigator will be funded under this announcement.

Application Type. See [Section IV.1](#) for application materials.

Special Date(s).

- Letter of intent, if it is submitted, is due 30 days after publication.
- A pre-application teleconference call will be conducted on February 27, 2015, from 2:00 – 3:30 pm Eastern Time to address prospective applicants' questions regarding FOA EH15-001, Environmental Health Specialists Network (EHS-Net) - Practice based research to improve food safety.
- PARTICIPANT ACCESS INFORMATION
- CALL DATE: February 27, 2015

- CALL TIME: 2:00 Eastern Time
- CALL DURATION: 1 hour 30 minutes
- CALL LEADER: Susan Neurath
- Toll-Free Number: (855)-644-0229
- Passcode: **8636049** #

Application Materials. See [Section IV.1](#) for application materials.

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations. Awards are made under the authorization of Section 301 of the Public Health Service Act [42 U.S.C. Section 241], as amended.

1. Background and Purpose

Background and Purpose

The National Center for Environmental Health (NCEH) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This program of research addresses the CDC Winnable Battles for Food Safety, "Healthy People 2020" priority areas of food safety and public health infrastructure, and the Food Safety Modernization Act.

CDC has identified reducing foodborne diseases as a winnable battle. With additional effort and support for evidence-based, cost-effective strategies that we can implement now, we will have a significant impact on our nation's health. Measurable outcomes of the program will be in alignment with the following performance goals for the National Center for Environmental Health: Prevent or reduce illness, injury and death related to environmental risk factors, and build and enhance effective partnerships to improve environmental health capacity.

CDC specific roles in the implementation of the Food Safety Modernization Act include enhancing foodborne disease surveillance systems by improving the collection, analysis, reporting and usefulness of associated data. These roles are to be implemented through governmental coordination and integration, evaluating and improving surveillance systems, and external stakeholder collaboration.

For more information, www.cdc.gov/winnablebattles/foodsafety/index.html, www.healthypeople.gov, <http://intra-apps.cdc.gov/fmo/>, <http://www.cdc.gov/foodsafety/fsma.html>

Environmental Health Specialists Network (EHS-NET) Research Opportunity Description

The focus of EHS-Net is to:

- Identify retail food safety issues
- Develop appropriate projects to address these issues
- Propose interventions and/or best practices based on the findings
- Disseminate findings

EHS-Net food safety activities include conducting applied behavioral and environmental epidemiologic research to identify environmental factors that contribute to disease transmission.

The focus of this research is to:

1. Identify and understand environmental factors associated with retail food safety, including food related illness and outbreaks.
2. Evaluate food safety service programs, providers and their activities;
3. Develop and disseminate the findings from EHS-Net projects to the environmental public health and food safety communities.

Research Objectives:

Staffing

1. Establish and maintain a qualified full-time senior staff position in the agency's food safety programs (*i.e.*, one full-time equivalent per program), with full responsibility for implementation and coordination of activities of the EHS-Net related to food safety. The person in this position must report directly to a senior environmental health official who has agency (State and/or local) authority to participate in EHS-Net activities. The person in this position also must have demonstrated leadership skills; technical knowledge and program experience with the food safety program; knowledge and understanding of the appropriate State environmental health program for food safety; and communication skills necessary to effectively promote and facilitate network activities. The person will be involved in study design; data collection, analysis, and interpretation; and publication of findings. The person will also be responsible for the accuracy, quality, and timely reporting of all data submitted to CDC's Environmental Health Specialists Network Information System (EHSNIS) (<http://www.cdc.gov/nceh/ehs/EHSNet/resources/ehsnis.htm>)
2. Identify an existing staff position in the health agency's program with responsibilities and organizational authority for foodborne disease surveillance. The individual should know and understand the epidemiology and surveillance of foodborne illnesses; knowledgeably conduct the epidemiology and surveillance of foodborne disease; inform and guide decisions concerning specific activities of the network; lead and coordinate proposed activities; and possess knowledge of and coordinate with the agency's environmental service program for food. The individual should be active in study design; data collection, analysis, and interpretation; and publication of findings.
3. Identify existing staff position(s) in State and/or local agencies with responsibility for carrying out specific EHS-Net activities. These persons should have the technical program experience needed to implement proposed activities; an understanding of the State food program; and the communication skills necessary to effectively implement proposed activities. State and/or local agencies are encouraged to have resources available to proficiently translate EHS-Net activities into other languages (e.g. Spanish or Chinese).

State Agency Collaboration and Planning

1. Strengthen the partnership between food safety, disease surveillance, and laboratory authorities in the State (*i.e.*, departments of health, departments of agriculture; agencies for institutional care, education, environmental protection, etc.) by establishing an interagency plan that identifies complementary responsibilities and support functions to carry out planned EHS-Net activities. The interagency plan should address policies and programs, technical assistance, and resources; and identify participating local agencies.
2. Define the geographical boundaries of the EHS-Net site. An EHS-Net site may include an entire State or a geographically defined area (or areas) within a State that, ideally, represents both rural and urban communities. Geographically defined areas may be represented as cities, urban and rural counties, townships, parishes, or districts as defined by the applicant or other partnering agency. Within this geographically defined area, local health agencies and/or other local agencies with regulatory responsibility for food must be identified as partners.
3. Within the State or geographically defined area, develop partnerships with State and/or local agencies and others to provide in-kind assistance or other cost-sharing support to complement the basic assistance obtained from CDC to support network activities.
4. Establish and/or sustain effective partnerships with other public or private organizations interested in addressing environmental health services issues related to their effectiveness in preventing disease (*e.g.*, universities, schools of public health, standard-setting organizations, multi-jurisdictional commissions with environmental responsibilities, community-based organizations, other Federal and State government agencies, research organizations, nongovernmental organizations and foundations).

Organize the network to:

1. Maintain the ability to accommodate changes in specific activities and priorities as the public health system's need for information changes, or as new and/or reemerging health problems or environmental issues emerge.
2. Include both rural and urban populations.
3. Have the capacity to conduct multiple, concurrent projects.
4. Enlist participation of local public health departments and/or other related agencies (*i.e.* departments of agriculture, environmental protection agencies) or private organizations with a role in protecting the public's health.

Operate the network as a consortium to function effectively as part of a national network of EHS-Net sites. Collaborate with CDC and other EHS-Net sites, through the EHS-Net steering committee and EHS-Net working groups, to establish priorities, coordinate and monitor projects, and ensure that projects address existing and emerging infections issues.

Ensure all potential interactions with study participants are properly reviewed to meet all appropriate federal, state and local requirements for protection of human subjects. Provide documentation of Institutional Review Board (IRB) approval for all relevant research projects involving human subjects.

Collect and submit samples (*i.e.*, food or environmental samples) as part of network activities to designated laboratories for evaluation. Laboratories may include State, Federal, or academic facilities, as appropriate for the study proposed and approved by the EHS-Net.

Manage, analyze, and interpret data from network activities; and publish and disseminate findings. Dissemination of findings includes, but is not limited to, presentations at local, regional and national public health and food conferences, such as the International Association of Food Protection, Conference for Food Protection, etc., and publication of articles in peer reviewed journals, and information on the EHS-Net website.

Propose and conduct activities subject to public health priorities identified at the annual EHS-Net Grantee meetings in collaboration with CDC and appropriate partner agencies or organizations. Collaborate with CDC and other EHS-Net network sites to develop and finalize protocols for activities. Obtain the appropriate IRB approvals for research involving human subjects for all participating sites.

Categories of Food Safety Activities:

1. Conducting environmental assessments when investigating foodborne illness outbreaks to inform continued improvements in the collection, reporting, analysis and use of assessment data in the identification and/or improvement or development of foodborne illness prevention activities or policies. This includes reporting data collected to CDC through the EHS-Net Web-based information system (see <http://www.cdc.gov/nceh/ehs/EHSNet/ehsnis.htm>), the National Voluntary Environmental Assessment Information System (see <http://www.cdc.gov/nceh/ehs/NVEAIS/index.htm>), and may also involve collection of food and/or environmental surface samples and submission to State, CDC, or other laboratories.
2. Building on previous EHS-Net research activities and findings (see <http://www.cdc.gov/nceh/ehs/EHSNet>), develop, implement, and evaluate interventions designed to identify and understand environmental factors associated with retail food safety, including foodborne illness. Possible activities that fall under this category include applied behavioral, food safety and environmental epidemiologic research. Other possible activities include conducting behavioral research on preventing restaurant workers from working when ill; improving hand-washing behaviors and minimizing bare hand contact with foods; and requiring trained, certified kitchen managers to be present during all hours of operation. Examples of other potential behavioral projects include identification of risky food preparation practices and environmental factors related to those practices; barriers and facilitators for implementation of intervention strategies by food workers or managers; barriers and facilitators for EHS as risk communicators and risk managers; barriers and facilitators for food safety programs in enforcing regulatory requirements; and development and evaluation of training materials or prevention messages for EHS, industry, or the public. Examples of potential environmental epidemiologic projects include descriptive epidemiology projects to determine the level of control of risk factors and status of food safety policies, and other studies to determine what factors and policies or combination prevent outbreaks of foodborne illness. Examples of potential food safety research may include development or evaluation of environmental sampling techniques for norovirus or other pathogens of interest; development or evaluation of pathogen-specific environmental sampling techniques or policies for investigations of foodborne illness outbreaks, or for use during routine evaluations to establish baseline levels of pathogen-specific contamination; or projects to assess the route of pathogen-specific cross-contamination.
3. Evaluating food safety programs and their activities. Potential projects would attempt to assess the effectiveness of food safety programs and/or specific activities in reducing risk factors for disease in the population served. Implementation and evaluation of pilot prevention and intervention projects (*i.e.*, evaluation of integrated communication projects designed to increase hand washing by food workers in

restaurants, or evaluation of hand washing behaviors and the impact on infectious diseases in institutional food service). Potential projects could include evaluation of the effects of food workers' or managers' food safety training programs on active managerial control of risk factors to foodborne illness outbreaks.

References: Food Safety Projects (see <http://www.cdc.gov/nceh/ehs/EHSNet/foodsafety.htm>)

Healthy People 2020 and other National Strategic Priorities

This program of research addresses the CDC Winnable Battles for Food Safety, “Healthy People 2020” priority areas of food safety and public health infrastructure, and the Food Safety Modernization Act.

Public Health Impact

CDC has identified reducing foodborne diseases as a winnable battle. With additional effort and support for evidence-based, cost-effective strategies that we can implement now, we can have a significant impact on our nation's health. Measurable outcomes of the program will be in alignment with the following performance goals for the National Center for Environmental Health: Prevent or reduce illness, injury and death related to environmental risk factors and build and enhance effective partnerships to improve environmental health capacity.

Relevant Work

NCEH's website on Food Safety (<http://www.cdc.gov/nceh/ehs/topics/foodsafety.htm>) highlights a number of their efforts to conduct surveillance of foodborne illness outbreaks, investigate the cause of foodborne illness outbreaks, and conduct research to develop best management practices to prevent foodborne outbreaks.

2. Approach

Objectives/Outcomes

Applications are expected to propose efforts designed to:

- Conduct foodborne outbreak environmental assessments and report findings to the National Voluntary Environmental Assessment Information System.
- Identify and improve our understanding of environmental factors associated with retail food safety.
- Evaluate food safety service programs, providers and their activities;
- Develop and disseminate findings from EHS-Net projects to the environmental public health and food safety communities.

Target Population

The research will be conducted in retail food establishments (e.g., restaurants, delis, cafeterias, schools, nursing homes, grocery stores). Specifically, the retail establishment kitchens will be observed and managers and workers will be interviewed. Thus, the target population of the research is retail food establishments.

Collaboration/Partnerships

This announcement seeks to continue the Environmental Health Specialists Network (EHS-Net) practice-based research studies to provide regulatory officials with science and data to implement policies and regulations that protect communities from foodborne illness outbreaks and to provide communities with safe food. In order to conduct this critical research, successful collaboration between both public health and regulatory agencies is required. Previous EHS-Net sites have modeled the necessary level of collaboration across multiple state and local agencies to accomplish this goal. Applicants are expected to develop collaborations pertinent to the proposed research plan. Applications are expected to include documentation of effective and well-defined working relationships with any organization and/or outside entity expected to participate in the proposed research. Collaborations and documentation of the collaborations are expected to ensure implementation and sustainability of the applicant’s proposed activities. Documentation of collaboration is illustrated by letters of support, memoranda of understanding or agreement, or interagency plans that detail the nature and extent of the involvement from the performing organization and outside entities. Applicants must submit documentation of all partnerships and collaborations with the application and include the documentation in the appendix.

Evaluation/Performance Measurement

Applicants are expected to provide measures of effectiveness that will demonstrate the accomplishment of the proposed project objectives. Measures of effectiveness must relate to the goals stated in the “Purpose” section of this announcement. Measures must be objective and quantitative and must measure the intended outcome.

Translation Plan

Research findings should be disseminated through publications, including articles in peer reviewed journals and “Research Briefs” for diverse audiences, as well as presentations at professional conferences and other venues. Applicants are encouraged to include other avenues of dissemination of findings other than publications and presentations to reach as diverse an audience as possible. An explanation for how the scientific findings could be translated into public health programs, policies or practice should be included.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: \$1,425,000

Anticipated Number of Awards: 8

NCEH intends to commit approximately \$1,425,000 in FY 2015 to fund up to eight applications. The maximum amount per award for the first 12-month budget period is \$178,125 (direct and indirect costs). The project period is expected to be five years. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received and approved.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: \$178,125 Per Budget Period

Award Floor: \$0 Per Budget Period

Total Project Period Length: 5 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments
County governments
City or township governments
Native American tribal governments (Federally recognized)

Governments:

U.S. Territory or Possession

Other:

Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Eligibility for this funding announcement is limited to applicants from governmental agencies that have the authority and responsibility to regulate and oversee retail food service including restaurants, delis, cafeterias, schools, etc. for food safety. These include State Governments or their Bona Fide Agents (includes the District of Columbia); Local Governments (County, City or Township) or their Bona Fide Agents; American Indian or Alaska Native Tribal Governments (federally-recognized or state-recognized); and Territorial Governments or their Bona Fide Agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau Governments.

Eligibility is limited to the agencies described above because this announcement seeks to continue the Environmental Health Specialists Network (EHS-Net) research activities. EHS-Net was developed to provide regulatory officials with science and data to implement policies and regulations that protect communities from foodborne outbreaks and to provide communities with safe food.

All applicants that include a partnership between various agencies must have or establish a Memorandum of Understanding (MOU) documenting the responsibilities and proposed activities of each organization that will contribute to the research efforts, public health evaluations, and retail food regulatory practices. This is important to ensure that the applicable state and local agencies responsible for governing, setting policies and regulating food are involved in the projects from the beginning. Having the responsible agencies involved in the research activities will help ensure that we are maximizing our ability to reduce foodborne illness. **The MOU must be submitted with the application and be included in the appendix.** If your application is incomplete or non-responsive to the special requirements listed in this section, it will be considered ineligible and will not be forwarded for review.

4. Justification for Less than Maximum Competition

Eligibility is only offered to agencies that have the governmental authority and responsibility to regulate and oversee retail food service. These agencies have the unique capacity to implement public policies and regulations to protect communities from foodborne outbreaks and to provide communities with safe food. Additionally, these agencies are uniquely positioned to establish the necessary level of collaboration across multiple agencies to accomplish the purpose and goals of EHS-Net, and the research objectives of this FOA. No other business, university, organization, etc. will be able to lead collaborative efforts to change or improve the delivery of environmental health programs developed for this purpose.

5. Responsiveness

- Applications will be considered nonresponsive if they exceed the page limitations or attachment limitations specified in this announcement.
- Applications that include proposals to collaborate with other federal, state, or local agency or organization, must include a memorandum of understanding (MOU) detailing the nature and extent of the working relationships and involvement that can be expected from each organization outside of the grantee's agency. **This documentation must be included in the appendix.**
- Applications will be considered nonresponsive if they do not meet the other criteria specified in this announcement.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](https://www.Grants.gov)
- [eRA Commons](https://www.eRA Commons)

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The “one-time” registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date.** Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at <https://www.sam.gov/index.html>.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. However, applicant institutions can submit only one grant application with the same principal investigator. Only one application per principal investigator will be funded under this announcement.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate “optional” components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled “PHS398.” Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.

3. Letter of Intent

Due Date for Letter of Intent: **03/12/2015**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Applicant

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

Jane Suen, DrPH

Scientific Research Official

for the National Center for Environmental Health, ATSDR, and NCIPC

Centers for Disease Control and Prevention (CDC)

4770 Buford Hwy, NE Mailstop F-63

Atlanta, GA 30341

Telephone: 770-488-4281

Email: JXS8@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

- 1. Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
- 2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
- 3. Research Strategy** – the research strategy should be organized under 3 headings: Significance,

Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)

5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table (for New Application ONLY)

9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan.

13. Consortium/Contractual Arrangements

14. Letters of Support

15. Resource Sharing Plan(s)

16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide

(http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 60 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a “submission receipt” email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:

If an application submission was unsuccessful, *the applicant* must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.
 - b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **04/10/2015**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (<http://www.archives.gov/federal-register/codification/executive-order/12372.html>). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process. Click on the following link to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spo/.

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>.

12. Other Submission Requirements and Information

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders:

All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization’s profile in the eRA Commons and for the System for Award

Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters “FWA” before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (<http://www.cdc.gov/about/organization/mission.htm>), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact

Reviewers will provide an overall 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.

Significance

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?

- Does this study address an important problem(s)?
- If the applicant achieves the aims of the application, how will it advance scientific knowledge, or food safety or public health practice?
- What will be the effect of these studies on the concepts, methods, technologies, or preventative interventions that drive this field?
- Does the proposal enlist participation of local public health departments and/or other appropriate government agencies or private organizations in a manner likely to improve food safety?

Investigator(s)

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?

- Does the applicant understand the objectives of this cooperative agreement program?
- Does the applicant understand the roles and responsibilities of participation in the EHS-Net?
- Are the investigators appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the principal investigator and other researchers?
- Does the investigative team bring complementary and integrated expertise to the project?
- Has the applicant identified key professional personnel for assignment to the EHS-Net and network projects?
- Has the applicant identified key professional personnel from other participating or collaborating institutions, agencies, and organizations outside the applicant's agency that will be assigned to EHS-Net activities?
- Is a curriculum vitae provided for each in the appendix?
- Does the applicant clearly state participants' roles in the management and operation of the EHS-Net?
- Does the applicant provide descriptions of participants' experience in conducting work similar to that proposed in this announcement?
- Does the applicant describe all support staff and services to be assigned to the EHS-Net?

Innovation

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

- Is the project original and innovative? For example: Does the project challenge existing paradigms, or food safety or public health practice; address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area? For example: Capturing data collected in the field often where internet access is limited or unavailable within mobile data collection forms via a mobile device (e.g. tablet, iPad, etc.) not requiring internet access.

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the

inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project?
- Does the application include an interagency plan between State health and food safety programs that defines each agency's responsibilities and support functions and, when appropriate, their active participation in EHS-Net projects as evidenced by collection and submission of data or specimens, or evidence of other specific contributions to EHS-Net projects?
- Are the proposed collaborations between the environmental health service program (food safety) and the disease surveillance program (foodborne) appropriate and defined with sufficient detail to be expected to identify projects that provide food safety programs with information assisting them with control of risk factors to illness and outbreaks?
- Does the applicant describe the requirements, responsibilities, problems, constraints, and complexities that may be encountered in implementing and coordinating EHS-Net activities related to food safety?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Does the applicant describe their plan for establishing and operating the EHS-Net?
- Does the applicant succeed in describing how they will function as part of a national network of EHS-Net sites?
- Does the applicant succeed in describing the level of involvement that will be provided by each partner?
- Does the applicant provide (in an appendix) letters of support indicating collaborators' commitments to participate in the EHS-Net, and describing their anticipated role?
- Does the applicant describe the ability to conduct research activities that address the needs and characteristics of the proposed EHS-Net site (i.e., demographic or language)?
- Does the applicant clearly identify the proposed organizational and operating structure and procedures for EHS-Net activities?
- Does the applicant describe the roles and responsibilities of all participating agencies, organizations, institutions, and individuals?
- Does the applicant describe plans to collaborate with CDC and other EHS-Net sites in the operation of the national network of EHS-Net sites? This includes project design and development (e.g., protocols), management and analysis of data, and synthesis and dissemination of findings.
- Does the applicant describe partnerships with necessary and appropriate organizations to establish and operate the proposed EHS-Net?
- Does the applicant describe proposed projects consistent with the guiding principles of the network and the public health needs?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Is there evidence of institutional support?
- Does the applicant describe whether/how the proposed work will relate to other programs sponsored by the agency, which are already in place or planned to support foodborne disease surveillance and food safety?
- Does the applicant describe whether/how the proposed work will relate to other programs sponsored by other agencies, which are already in place or planned to support foodborne disease surveillance and food safety?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, 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 [45 CFR Part 46](#), the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your 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. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research

(http://www.cdc.gov/maso/Policy/Policy_women.pdf and

<http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://www.cdc.gov/maso/Policy/policy496.pdf>).

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. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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 scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans

HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25.

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. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Balance of the proposed research relative to the HHS/CDC/NCEH programs and priorities.
- Significance of the proposed activities in relation to the priorities and objectives stated in “Healthy People 2020”.
- Significance of the proposed activities in relation to CDC’s Winnable Battles related to Food Safety.

- Significance of the proposed activities in relation to HHS's National Prevention Strategy Strategic Priority of Healthy Eating.
- Applicant's demonstrated ability to work collaboratively across food safety agencies in their state to conduct applied research activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement ([http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award ([http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf](http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf)).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-3: Animal Subjects Requirements](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[AR-12: Lobbying Restrictions](#)

[AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities](#)

[AR-14: Accounting System Requirements](#)

[AR-16: Security Clearance Requirement](#)

[AR-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR 32 –; FY 2012 Enacted General Provisions](#)

ARs applicable to Conference Awards:

[AR-20: Conference Support](#)

[AR-27: Conference Disclaimer and Use of Logos](#)

Organization Specific ARs:

[AR-8: Public Health System Reporting Requirements](#)

[AR-15: Proof of Non-profit Status](#)

[AR 23: Compliance with 45 C.F.R. Part 87](#)

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: <http://www.archives.gov/>.

To view brief descriptions of relevant CDC requirements visit: [http:// www.cdc.gov/ od/pgo/funding/ grants /additional req.shtm](http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm).

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

[http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol memo.html](http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html))

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov ([http:// www.usaspending. gov/](http://www.usaspending.gov/)). For the full text of the requirements, please review the following website: [https:// www.frs.gov/](https://www.frs.gov/).

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: [http:// www.plainlanguage.gov/plLaw/index.cfm](http://www.plainlanguage.gov/plLaw/index.cfm).

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- <http://www.gsa.gov/graphics/pbs/>

[Guidelines for Federal Concessions and Vending Operations.pdf](#)

- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>

- <http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

This FOA is for a cooperative agreement. Under the cooperative agreement mechanism, the Centers for Disease Control and Prevention's (CDC) purpose is to support the awardee's activities. Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more individuals funded by a cooperative agreement will be subject to PRA determination and may or may not be subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). PRA applicability will depend on level of CDC involvement with the development, collection and management of information/data.

The PD(s)/PI(s) will have the primary responsibility to:

- Establish a program to meet the research objectives described in this Funding Opportunity Announcement.
- Establish and maintain a qualified, staff to meet the research objectives described in Part 2, Section I.
- Strengthen the partnership between food safety, disease surveillance, and laboratory authorities in the State and with the participating local agencies.
- Establish the EHS-Net in a defined area and develop the necessary partnerships to support network activities.
- Operate effectively within the network consortium to include collection and submission of samples to designated laboratories; collection, management, analysis, and interpretation of data from network activities; dissemination of research findings; and in collaboration with CDC and other network sites, propose and conduct research activities identified at EHS-NET grantee meetings.
- Ensure all potential interactions with study participants are properly reviewed to meet all appropriate federal, state and local requirements for protection of human subjects. Provide documentation of Institutional Review Board (IRB) approval for all relevant research projects involving human subjects.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Provide general coordination for the EHS-Net.
- CDC will serve as the primary contact for and seek input from the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA) and other Federal agencies with expertise in food safety program areas and interest in EHS-Net

activities.

- CDC will seek input from participating food programs to determine the training needs of EHS. Identify existing training resources and develop new training materials as may be appropriate.
- Provide technical assistance by participating in foodborne illness outbreak investigations as requested by participating States.
- Provide consultation, and scientific and technical assistance in the operation of the EHS-Net, and in designing, implementing, and evaluating individual EHS-Net projects.
- Assist with analysis and interpretation of data from EHS-Net projects.
- Participate in the dissemination of findings and information stemming from EHS-Net projects and assist recipients when necessary.
- Assist in monitoring and evaluation of scientific and operational accomplishments of the EHS-Net and progress in achieving the purpose and overall goals of this program by conducting conference calls, site visits, hosting meetings of participants and conducting a process evaluation of the EHS-Net.
- Assist in the development of research protocols for Institutional Review Board (IRB) review by all institutions participating in any research project involving human subjects and CDC scientists as co-investigators.
- CDC project managers will ensure that all relevant organizational IRBs have given their written approval. When appropriate, the CDC IRB will review and approve research protocols.
- CDC will host an annual EHS-NET Grantee Meeting to determine, review, and approve as a consortium program priorities. Successful applicants are expected to participate in this meeting.
- Additionally, an HHS/CDC agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the notice of award.

Areas of Joint Responsibility include:

- Applicants and CDC staff will work collaboratively in the conduct of this multi-site research.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over \$25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all

subawards over \$25,000. See the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) for additional information on this reporting requirement.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, **is due 90 to 120 days prior to the end of the current budget period**. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period**.

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (<http://grants1.nih.gov/grants/funding/2590/2590.htm>) <http://grants.nih.gov/grants/funding/2590/2590.htm>: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.
- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include:*
 - How will the scientific findings be translated into public health practice or inform public health policy?
 - How will the project improve or effect the translation of research findings into public health practice or inform policy?

- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?
- **Public Health Relevance and Impact (1 page maximum).** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include:*
 - How will this project lead to improvements in public health?
 - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
 - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- **Current Budget Period Financial Progress:** Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- **New Budget Period Proposal:**
 - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
 - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).
- **New Budget Period Budget:** Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- **Publications/Presentations:** Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- **IRB Approval Certification:** Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at [http:// grants.nih.gov/ grants/forms.htm](http://grants.nih.gov/grants/forms.htm). For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https:// commons. era.nih.gov/ commons/](https://commons.era.nih.gov/commons/)). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: <http://era.nih.gov/commons/>. Organizations not yet registered can go to [https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp](https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp) for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: [http:// era.nih.gov/ commons /index.cfm](http://era.nih.gov/commons/index.cfm).

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee’s final report should include:

- **Research Aim/Project Overview:** The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- **Translation of Research Findings:** The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- **Public Health Relevance and Impact:** This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[Grants.gov Customer Support](#) (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

Email: support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

[eRA Commons Help Desk](#) (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)

Procurement and Grants Office

Telephone 770-488-2700

Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

Susan Neurath, PhD

Scientific Program Officer

for the National Center for Environmental Health, ATSDR, and NCIPC

Centers for Disease Control and Prevention (CDC)

Telephone: 770-488-3368

Email: SFN8@cdc.gov

Peer Review Contact(s)

Jane Suen, DrPH

Scientific Review Officer

for the National Center for Environmental Health, ATSDR, and NCIPC

Centers for Disease Control and Prevention (CDC)

Telephone: 770-488-4281

FAX: 770-488-4422

Email: JXS8@cdc.gov

Financial/Grants Management Contact(s)
Kevin Heath
Procurement and Grants Office (PGO)
Telephone: 770-488-1120
Email: YFU6@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations. Awards are made under the authorization of Section 301 of the Public Health Service Act [42 U.S.C. Section 241], as amended.

Successful grantees will be permitted expanded authorities in the administration of this award as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, §200.308(d)(4).

Amendment 1 Questions and Answers from the EH15-001 Pre-Application Conference Call February 27, 2015

Please note that the information below does not represent an actual transcript of the conversation. The information has been edited for both accuracy and clarity.

1. Does this FOA pertain to EHS-Net practice partner applicants or only research partners?
 - a. This announcement is for a research cooperative agreement. However, it is focused on practice-based research.
2. County governments are listed as an eligible category, but the document is written as if only State governments are expected to apply (see page 5, State Agency Collaboration and Planning). Would a County health department (from a very geographically large county with both rural and urban characteristics) be expected to be able to submit a competitive proposal?
 - a. Yes.
3. What actually is meant by “practice” when compared to “research”?
 - a. Practice: to identify and control a health problem or improve a public health program or service
 - b. Practice-based research: to develop or contribute to generalizable knowledge that improves public health practice

4. Will the applicant need to identify the specific intervention to be evaluated in the research component? Or will the problem and/or intervention be identified in collaboration with the consortium?
- a. The applicant is expected to identify a problem/intervention for their site specific activities. The awarded sites will collaboratively decide on the multi-site projects.
5. Is a “strategic” plan a required component of the application?
- a. No. However, a Research Plan is required. Please see page 14 of the FOA for a brief discussion on the expectations for the Research Strategy section and then consider the questions listed under each review criteria (pages 18-20).
6. Are all states competitive for this award?
- a. Yes.
7. On the Research Plan Component, does the application need to include the relevant IRB approval for the site-specific intervention planned?
- a. No. The application does not need to include the relevant IRB approval for the specific activities proposed. However applicants are expected to describe the methods that would be used to ensure the protection of human subjects.
- b. Please note that grantees are expected to have documentation of IRB approval at the time the award is made. Grantees without this documentation will have a funding restriction placed on the award until the IRB approval documentation is submitted. No human subject activities may be conducted without appropriate approval. As a result, the amount of the funding restriction will be commensurate with the amount of funding required to conduct the activities involving human subjects.
8. Does the application need to include specific information about the methods used to ensure inclusion of women and minorities?
- a. The application is expected to discuss the plans in a general sense; however, the Enrollment Table describing the composition of the study population must be submitted with the application. The Enrollment Table should be based on what might be the expected enrollment. The expected enrollment is based on the demographics of the target population.
9. How should the budget show the “in kind” support for key personnel?
- a. Use the budget tables and Standard Form (SF) 424 form for research. Show these key personnel, with their percent of effort relevant to the study, as “in kind” support with no budget cost or fringe benefits associated with their participation. The budget justification should include a description of their role in the project. For key personnel who will be “in kind”, it would be helpful to document departmental or agency approval for the in kind effort in letters of support.
10. Our institution will have a large number of collaborations. We have letters of support for each collaboration but we will exceed the limit of 10 pdf files in the appendix if we submit each letter of support. How can I submit all of the letters of support?
- a. Within the PHS 398 Research Plan, there is a specific location to attach a pdf file of the letters of support.

List of Changes:

Page 9, the maximum award amount, per grantee, for the first 12-month budget period was corrected to \$178,125. This sentence now reads “NCEH intends to commit approximately \$1,425,000 in FY 2015 to fund up to eight applications. The maximum amount per award for the first 12-month budget period is \$178,125 (direct and indirect costs).”