



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-20-001

Application Due Date: 03/06/2020

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

RFA-EH-20-001

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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

Notice of Funding Opportunity (NOFO) Title

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

Activity Code

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

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-EH-20-001

Assistance Listings (CFDA) Number(s)

93.070

Category of Funding Activity:

Health

NOFO 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. 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. For information on EHS-Net activities, please visit our web page at: <https://www.cdc.gov/nceh/ehs/ehsnet>.

The purpose of Amendment 1 to this NOFO is to update the application submission deadline to no later than 5:00 PM U.S. Eastern Time on March 6, 2020, to update the expected project start date to September 30, 2020, and to provide additional clarifying information based on questions received from potential applicants during the Pre- Application Conference Call held on January 7, 2020. A summary of these questions and answers can be found in Section VIII. Other Information, of the amended NOFO.

Key Dates

Publication Date:

To receive notification of any changes to RFA-EH-20-001, 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:

01/28/2020

Application Due Date:

03/06/2020

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time 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:

06/03/2020

This is an approximate date.

Secondary Review:

07/16/2020

This is an approximate date.

Estimated Start Date:

09/30/2020

This is an approximate date.

Expiration Date:

04/30/2020

Due Dates for E.O. 12372:

Due no later than 60 days after the application receipt date.

Required Application Instructions

****ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED****

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) 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 20 pages.

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

Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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

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. 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. For information on EHS-Net activities, please visit our web page at: <https://www.cdc.gov/nceh/ehs/ehsnet>.

This Environmental Health Specialists Network (EHS-Net) research opportunity seeks to develop and sustain a network of environmental health program staff, in collaboration with epidemiologists and other public health professionals, to identify retail food safety research practice-based priorities focused on identifying and preventing foodborne illness risk factors, and to conduct the research. EHS-Net research will contribute to:

- Identification of foodborne illness risk factors associated with retail food establishments,
- Identification of interventions to address those risk factors and reduce foodborne outbreaks (including food safety policies),
- Improvement of environmental health practice in the area of retail food safety.

This research opportunity will require three primary activities for those sites participating in EHS-Net. These are:

- Identifying and conducting multisite retail food safety practice-based research projects; all EHS-Net sites will participate in developing and conducting these projects.
- Identifying and conducting single-site retail food safety practice-based projects; these projects will be unique to each site and will address the needs and priorities of the site.

- Collecting and reporting data from the environmental health component of foodborne outbreak investigations to NCEH's National Environmental Assessment Reporting System (NEARS). These data, when aggregated and analyzed, provide valuable information about the causes and prevention of foodborne illness outbreaks.

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 \$1,540,700 in FY 2020 to fund up to eight applications. The maximum amount per award for the first 12-month budget period is \$192,587 (direct and indirect costs). Awards issued under this NOFO 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 amount of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, and proposed 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 \$1,540,700 (direct and indirect costs) and the estimated total funding for the entire project period is expected to be \$7,703,500 (direct and indirect costs). The project period is expected to run from 09/01/2020 to 08/31/2025.

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 NOFO; their names must appear on the face page of the application. However, one principal investigator must be designated as the contact PI. All PD/PIs must include their eRA Commons Identification in the Credential Field of the Senior/Key Person Profile Component of the SF424 (R&R) Application Package. 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).

- A **pre-application teleconference call** will be conducted on January 7, 2020 to address questions from prospective applicants regarding NOFO RFA-EH-20-001, "Environmental Health Specialists Network (EHS-Net)". The call will begin at 1:00 PM Eastern Standard Time (EST) and end at 2:00 PM Eastern Standard Time (EST), or sooner if all participant questions are addressed. Questions and answers from the discussion will be included in an amended NOFO to be published approximately 2 weeks after the call.

Participant Access Information

- Call Date: January 7, 2020
- Call Start Time: 1:00 PM Eastern Standard Time (EST)
- Call End Time: 2:00 PM Eastern Standard Time (EST)
- Call Leader: Daniel Holcomb, Scientific Program Official
- Toll-Free Number: 1-866-916-0413
- Conference Passcode: 52108552

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 Section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, and section 391 (a) [42 U.S.C. 280 b(a)] of the Public Service Health Act, as amended.

1. Background and Purpose

Background:

CDC/NCEH first funded EHS-Net in 1999, with the goal of establishing a consortium of federal, state, and local environmental health and epidemiological staff to identify and address retail foodborne illness risk factors. CDC/NCEH has funded state and local health departments to participate in EHS-Net in five-year cycles. Thus, the state and local EHS-Net sites change with each cycle. Together with CDC, U.S. Department of Agriculture (USDA), and Food and Drug Administration (FDA) representatives, EHS-Net sites identify its retail food safety priorities for the funding cycle, and conduct practice-based research activities to address those priorities.

EHS-Net is unique in its ability to collect real-time data on food safety policies and practices in retail food establishments. It relies on staff from environmental health programs; these staff are

experienced and invested in retail food safety and are best-positioned to identify retail food safety research priorities, conduct the research, analyze and interpret the data, and disseminate research findings. Indeed, since its founding in 2000, EHS-Net has published 43 scientific articles based on both individual and multisite studies.(See the Revelant Work section for more detail.)

Findings from EHS-Net research projects have influenced retail food safety and foodborne illness and outbreak prevention; EHS-Net findings have been used to inform significant, national food safety policy and practice guidelines, including the FDA Food Code and USDA-FSIS guidance on controlling *Listeria monocytogenes*. (See the Revelant Work section for more detail.)

Because of EHS-Net's continuing ability to address important gaps in retail food safety, and its ongoing effectiveness in collecting, analyzing, interpreting and disseminating food safety data, NCEH wishes to support another EHS-Net five-year cooperative agreement.

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

Purpose:

This Environmental Health Specialists Network (EHS-Net) research opportunity seeks to develop and sustain a network of environmental health program staff, in collaboration with epidemiologists and other public health professionals, to identify retail food safety research practice-based priorities focused on identifying and preventing foodborne illness risk factors, and to conduct the research. EHS-Net research will contribute to:

- Identification of foodborne illness risk factors associated with retail food establishments,
- Identification of interventions to address those risk factors and reduce foodborne outbreaks (including food safety policies),
- Improvement of environmental health practice in the area of retail food safety.

This research opportunity will require three primary activities for those sites participating in EHS-Net. These are:

- Identifying and conducting multisite retail food safety practice-based research projects; all EHS-Net sites will participate in developing and conducting these projects.
- Identifying and conducting single-site retail food safety practice-based projects; these projects will be unique to each site and will address the needs and priorities of the site.
- Collecting and reporting data from the environmental health component of foodborne outbreak investigations to NCEH's National Environmental Assessment Reporting System (NEARS). These data, when aggregated and analyzed, provide valuable information about the causes and prevention of foodborne illness outbreaks.

Healthy People 2020 and other National Strategic Priorities

This program of research addresses the established CDC Food Safety Winnable Battle 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 Water, Food, and Environmental Health Services Branch has a 20-year history of funding state and local public health programs to successfully develop and conduct individual and multisite research projects related to food safety. EHS-Net was first funded in 2000; since then, EHS-Net has published 43 scientific articles based on both individual and multisite projects. A select few of these articles are listed below.

- Brown L, Hoover E, Faw B, Hedeem N, Nicholas D, Wong M, et al. [*Food safety practices linked with proper refrigerator temperatures in retail delis.*](#) Foodborne Pathog Disease. 2018;15(5):300-7
- Cates SC, Muth MK, Karns SA, Penne MA, Stone CN, Harrison JE. [*Certified kitchen managers: do they improve restaurant inspection outcomes?*](#) J Food Prot. 2009;72(2):384-91.
- Green L, Radke V, Mason R, Bushnell L, Reimann D, Mack J, Motsinger M, Stigger T, Selman C. [*Factors related to food worker hand hygiene practices.*](#) J Food Prot. 2007;70(3):661-666.
- Radke T, Brown LG, Faw B, Hedeem N, Matis B, Perez P, et al. [*Restaurant food allergy practices & six selected sites, United States, 2014.*](#) MMWR. 2017;66(15):404-7
- Sumner S, Brown LG, Frick R, Stone C, Carpenter LR, Bushnell L, et al. [*Factors associated with food workers working while experiencing vomiting or diarrhea.*](#) J Food Prot. 2011;74(2):215-20.
- Wong M, McKelvey W, Ito K, Schiff C, Jacobson JB, Kass D. [*Impact of a letter-grade program on restaurant sanitary conditions and diner behavior in New York City.*](#) Am J Public Health. 2015;105(3):e81-7

Findings from EHS-Net research projects have influenced retail food safety and foodborne illness and outbreak prevention; EHS-Net findings have been used to inform significant, national food safety policy and practice guidelines. Specifically:

- EHS-Net findings on links between kitchen manager certification and food safety were used to support changes to the 2017 *FDA Food Code* that strengthened certification requirements.
- The CDC-funded Council to Improve Foodborne Outbreak Response’s (CIFOR) used EHS-Net findings on investigation practices linked to outbreak contributing factor identification to inform their *Guidelines for Foodborne Disease Outbreak Response*, a

comprehensive best-practices resource for federal, state, and local agencies that investigate foodborne outbreaks.

- EHS-Net's investigation practice findings also informed the development of CDC's new version of Epi-Ready, an influential training on foodborne outbreak investigation for environmental and public health professionals.
- USDA's Food Safety and Inspection Service (FSIS) used EHS-Net findings on retail deli food safety practices in the development of their *Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens*, a guidance document for retailers.
- These findings were also used in the development of the Interagency (CDC, FDA, USDA-FSIS) *Retail LM Action Plan* to reduce the risk of *listeriosis* via promotion of best practices in retail delis.
- USDA-FSIS used EHS-Net study findings to inform the development of a new rule that requires retail establishments to maintain beef grinding logs to improve FSIS's ability to trace the source of foodborne outbreaks.

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

Outcomes will be achieved through three primary approaches. First, successful applicants will collaborate with other applicants and EHS-Net partners to identify, develop, and conduct practice-based retail food safety multisite research projects. Second, successful applicants will identify, develop, and conduct practice-based retail food safety projects unique to their site.

Both multisite and individual site projects could involve a variety of approaches. Examples include:

- Collecting interview and observation descriptive data on food workers' food safety practices in retail establishments.
- Developing, implementing, and evaluating interventions to improve retail food safety.
- Evaluating food safety program activities, such as retail inspection and outbreak investigation practices.
- Collecting linking, and analyzing environmental health epidemiologic data to identify relationships between food safety policies and regulations and outbreak occurrence and size.

Because of its prevalence in retail establishments, project activities focused on norovirus investigation and prevention are encouraged. Likewise, activities focused on the most frequent contributing factors to retail-related outbreaks, including contamination of food by ill workers and improper use of time as temperature control, are encouraged. Projects focused on the use of environmental sampling as an investigative tool are also encouraged.

A third approach will be used to achieve primary outcomes--successful applicants will conduct environmental assessments when investigating foodborne outbreaks and will report these

assessment data to CDC's National Environmental Assessment Reporting System (NEARS). These environmental assessment data, when aggregated and analyzed, will provide valuable information about the causes and prevention of foodborne illness outbreaks.

Objectives/Outcomes

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.
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/Locality 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. (See Common Rule Requirements in Section VI (4))

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 grant recipient 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) Practice-based retail food safety research projects. These projects should be aimed at identifying foodborne illness risk factors associated with retail food establishments, identifying interventions to address those risk factors and reduce foodborne outbreaks (including food safety policies), and evaluating or improving environmental health programs and practice in retail food safety. These projects can include applied behavioral, food safety, or environmental epidemiological approaches. Examples of such projects include, but are not limited to:

- Describing or improving retail establishments' active managerial control over food safety or food safety management systems.
- Describing or improving practices that pose foodborne illness risk in retail food establishments, such as poor worker hand hygiene, workers working while ill, inadequate temperature control of food, and inadequate cleaning and sanitizing of food surfaces and equipment.
- Identifying gaps in formal food safety policies in retail food establishments.
- Identifying retail establishment characteristics associated with retail food safety.
- Identifying and evaluating interventions to reduce retail foodborne illness risk/improve food safety.
- Identifying gaps in retail inspection or outbreak investigation practices.
- Investigating and preventing norovirus transmission and outbreaks.
- Developing and evaluating environmental sampling protocols and methods.
- Assessing effectiveness of food safety programs in reducing foodborne illness risk factors.

2) Conducting environmental assessments during foodborne illness outbreak investigations. Data from these environmental assessments will inform continued improvements in the collection, reporting, analysis, and use of environmental assessment data in the identification, development, and improvement of foodborne illness prevention activities. This includes reporting data collected to CDC through the National Environmental Assessment Reporting System (NEARS) (See <https://www.cdc.gov/nceh/ehs/nears/>) and may also involve collection of food or environmental surface samples and submission to state, CDC, or other laboratories.

References: See "Relevant Work", and Food Safety Projects <http://www.cdc.gov/nceh/ehs/EHSNet/foodsafety.htm>

Outcomes will be achieved through three primary approaches. First successful applicants will collaborate with other applicants and EHS-Net partners to identify, develop, and conduct practice-based retail food safety multi-site research projects. Second, successful applicants will identify, develop, and conduct practice-based retail food safety projects unique to their site.

Primary Outcomes to be achieved with funded research:

Expected outcomes of this project include

- identification of retail foodborne illness factors and gaps in retail food safety policies and practices,
- identification of interventions to address those risk factors and reduce foodborne outbreaks, and
- improvement of environmental health practice in the area of retail food safety.

Example outcomes include:

- Identified prevalence of food preparation practices that pose foodborne illness risk in retail food establishments, such as poor worker hand hygiene, inadequate temperature control of food, and inadequate cleaning and sanitizing of food surfaces and equipment.
- Identified prevalence of the lack of formal food safety policies in retail food establishments.
- Retail establishment characteristics associated with retail food safety. For example, past EHS-Net research has consistently found that retail establishments with food safety certified kitchen managers have better food safety practices.
- Identified methods to reduce retail foodborne illness risk/improve food safety. For example, EHS-Net has recently begun a study designed to evaluate the effectiveness of an education intervention to improve retail practices concerning employees working while ill.
- Identified improvements in environmental public health practice. An example: development and delivery of training to food safety program staff, informed by findings about gaps in food safety program staff's inspection practices, on identifying food safety violations on parasite destruction in sushi restaurants. Identification of gaps in outbreak investigation practices, based on collection and analysis of outbreak environmental assessment data reported to NEARS.

Target Population

NOFO applicants will be conducting research that can inform retail safety interventions and policies and improve food safety practices in retail food establishments. The majority of the population is impacted by retail food safety; 61% of U.S. adults recently reported they ate dinner at a restaurant at least once in the past week. Some members of the population are at greater risk from foodborne illness; these include children, older people, and those with reduced immunity.

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.

Environmental health, epidemiology, and laboratory programs within health departments all play a critical role in retail food safety, particularly in the area of outbreak investigation. Thus, successful applicants need to have and maintain collaborative partnerships among these three programs. Additionally, in some states, collaboration among local and state health departments is important to retail food safety. For example, in some states, local health department staff are responsible for conducting retail food safety inspections, while state health department staff are responsible for investigating outbreaks. As such, successful applicants need to have and maintain collaborative partnerships within their state. Finally, EHS-Net success is dependent upon the ability of its members to collaborate with one another to identify retail food safety research priorities, conduct the multisite research, analyze the data, and interpret and disseminate findings from the research. Thus, successful applicants need to be able to develop and maintain collaborative partnerships within the network.

Documentation of collaboration(s) must be 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 an evaluation and performance measurement plan with measures of effectiveness. The plan should demonstrate the feasibility of accomplishing proposed project objectives. Effectiveness measures should relate to the goals in the Purpose section of this announcement and measure the intended outputs and outcomes described. Outcomes to be evaluated should be clearly described. Performance measures could include the number of participants in a study, study participation rates, and types of data collected.

Translation Plan

Research findings should be disseminated through publications, including journal articles, for diverse audiences, and presentations at professional conferences and other venues. For multisite research projects, applicants will be expected to participate in work groups focused on disseminating and translating the research. Applicants are encouraged to consider other methods and venues to disseminate findings, such as infographics and convened meetings of stakeholders. A key outcome of this research will be to translate findings into actionable public health efforts; therefore, applicants should provide a description of how findings could be translated into policies and practices.

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:

\$7,703,500

Anticipated Number of Awards:

8

NCEH intends to commit approximately \$1,540,700 for direct and indirect costs in FY2020 to fund up to nine (8) awards. The maximum amount per award for the first 12-month budget period is \$192,587 (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 NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award ceiling and floor are for the first 12-month budget period only.

Award Ceiling:

\$192,587 Per Budget Period

Award Floor:

\$0 Per Budget Period

Total Period of Performance Length:

5 year(s)

Throughout the Period of Performance, 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

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. Additional Information on Eligibility

N/A

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

The Letters of Support section must include evidence of effective and well-defined working relationships between the awardee institution and any organizations or outside entities expected to partner in the proposed research, particularly those partners providing access to needed data. This should be evidenced by letters of support, or memoranda of understanding or agreement detailing the nature and extent of the involvement from the recipient organization and outside entities. **Applications that do not meet this requirement will be considered nonresponsive and will not be forwarded for review.**

The biosketch of the PI must include documentation of an advanced degree (Masters or doctorate) in environmental or public health, epidemiology or other related science, and experience in retail food safety. **Applications that do not meet this requirement will be considered non-responsive and will not be forwarded for peer review.**

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/>.

- [Grants.gov](https://www.Grants.gov)
- 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 Principle Investigator (PD/PI) 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 eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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 recipient 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 recipient 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>), applications received in response to the same Notice of Funding Opportunity 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 NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

As defined in the HHS Grants Policy Statement, (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>), applications received in response to the same Notice of Funding Opportunity 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 NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Applicant institutions may not submit applications with the same, or similar, proposed research to two or more funding opportunities from CDC. Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same principal investigator. Only one application per principal investigator will be funded under this announcement. If two or more applications from the same PI are received, the only application that will be submitted for review will be the first application received based on the time and date stamp for submission in Grants.gov. (<http://www.grants.gov>).

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit <https://public.era.nih.gov/assist> where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process. If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: <https://era.nih.gov/erahelp/assist>. Additional support is available from the NIH eRA Service desk via:

- E-mail: <http://grants.nih.gov/support/index.html>

- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide <http://grants.nih.gov/grants/how-to-apply-application-guide.htm> and here: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf>, except where instructed in this Notice of Funding Opportunity 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 package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate “optional” components. When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

3. Letter of Intent

Due Date for Letter of Intent: **01/28/2020**

The Letter of Intent (LOI) is not required, but it helps us to plan and relegate appropriate resources for the Peer Review process. Prospective applicants are asked to submit a letter of intent that includes the following information:

- contact information (name, title, address, phone, E-mail, etc.)
- affiliation
- NOFO number
- key personnel list
- a brief description of your intended research or proposed investigation and
- a positive statement of your intent to apply for a grant under this NOFO

The letter of intent should be sent to:

Mikel Walters, PhD
Scientific Review Officer for RFA-EH-20-001
National Center for Environmental Health, ATSDR, and NCIPC
Centers for Disease Control and Prevention (CDC)
4770 Buford Hwy, NE, Mailstop S106-9, Atlanta, GA 30341
Telephone: 404-639-0913
Email: NCIPC_ERPO@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package

associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

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 components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf> and <http://grants.nih.gov/grants/how-to-apply-application-guide.htm> for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, 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 NOFO.

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 time line.

4. Progress Report Publication List (for Continuation ONLY)

Other Research Plan Sections

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan.

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Authentication of Key Biological and/or Chemical Resources

12. Appendix

All instructions in the SF424 (R&R) Application Guide <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf> and here:

<http://grants.nih.gov/grants/how-to-apply-application-guide.htm> must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP)

in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds. The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

Examples of DMPs may be found here: USGS, <http://www.usgs.gov/products/data-and-tools/data-management/data-management-plans>

DATA MANAGEMENT PLAN

CDC/ATSDR policy requires that the public health data collected or generated using CDC/ATSDR funds should be made readily available for scientific communities and/or the public. Awardees who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate.

CDC/ATSDR requires federal fund recipients for projects and programs that involve new data collection or generation to develop and submit a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award. For purposes of this notice, “public health data” means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This requirement ensures that CDC/ATSDR is in compliance with the following: Office of Management and Budget (OMB) memorandum titled “Open Data Policy–Managing Information as an Asset” (OMB M-13-13); Executive Order 13642 titled “Making Open and Machine Readable the New Default for Government Information”; and the Office of Science and Technology Policy (OSTP) memorandum titled “Increasing Access to the Results of Federally Funded Scientific Research” (OSTP Memo).

Additional Requirement-25: Data Management and Access <https://www.cdc.gov/grants/addit>

[ionalrequirements/ar-25.html](#) outlines the components of a DMP and provides additional information for awardees regarding the requirements for data accessibility, storage, and preservation. The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

A DMP should include, at a minimum, following information:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights).
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use;
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified; and
- If applicants who contend that the public health data they collect or create are not appropriate for release, they must justify that contention in the DMP (for example, privacy and confidentiality considerations).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

The DMP is considered a living document that will require updates throughout the lifecycle of the project. Awardees should update their DMP to include any updates to the project's data collection and reflect progress or issues with planned data collection. The updates to DMP should be submitted as required for each reporting period. Awardees must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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 NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 20 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. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

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 <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf>.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.

Organizations must submit applications using the ASSIST web-based application preparation and submission process.

ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.

Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time 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).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:

Toll-free: 1-866-504-9552; Phone: 301-402-7469

<http://grants.nih.gov/support/index.html>

Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:

Toll-free: 1-800-518-4726

<https://www.grants.gov/web/grants/support.html>
support@grants.gov

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

It is important that applicants complete the application submission process well in advance of the due date time.

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. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b
2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
 - b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **03/06/2020**

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:
https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-_Review-_SPOC_01_2018_OFFM.pdf.

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,

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.

In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (<https://www.cdc.gov/grants/additionalrequirements/ar-35.html>).

For more information on expanded authority and pre-award costs, go to: <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>. CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please

see: <https://www.cdc.gov/grants/additionalrequirements/ar-25.html> for revised AR-25.

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at <https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf>, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (<https://www.fapiis.gov/>), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-

1132 annually. This questionnaire, which is located at <https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf>, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. Upload the questionnaire and supporting documents as an attachment in the "12. Other Attachments" section of the "RESEARCH & RELATED Other Project Information" section of the application. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- <http://era.nih.gov/erahelp/ASSIST/>

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS 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](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?

- How well does the application address the roles and responsibilities of participation in the EHS-Net?
- If successfully completed, to what extent will the proposed research the applicant achieves the aims of the application, how will it advance the scientific knowledge, or food safety or public health practice?
- If the applicant achieves the aims of the application, how well 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?
- How well 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?
- Does the applicant have the legal/regulatory authority to regulate retail food service establishments in their jurisdiction and collect data from retail food safety programs, evidence-based interventions and policies, and investigate foodborne outbreaks?

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?

- 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 and support staff for assignment to the EHS-Net and network projects?
- How much experience do the applicant's key personnel have working as part of a national network of EHS-Net sites?
- 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 key professional?
- To what extent does the applicant clearly state participants' roles in the management and operation of the EHS-Net?
- To what extent does the applicant provide descriptions of participants' experience in conducting work similar to that proposed in this announcement?

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 proposed research innovative and yet offer a reasonable potential of meeting the Purpose and Research Objectives of this NOFO?

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?

- Does the applicant demonstrate that they have the governmental authority and responsibility to regulate and oversee retail food service establishments in their jurisdiction? The success of this research is directly related to the applicant's ability and capacity to implement public policies and regulations to protect communities from foodborne outbreaks and to provide communities with safe food.
- Is the applicant 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 NOFO?
- Does the application include an interagency plan between State health and food safety programs that clearly defines each agency's responsibilities and support functions?

- To what extent does the applicant describe the participation of State health and food safety programs in EHS-Net projects and, when appropriate, their active participation in EHS-Net projects as evidenced by the collection and submission of data or specimens, or evidence of other specific contributions to EHS-Net projects?
- To what extent are the proposed collaborations between the environmental health service program (food safety) and the disease surveillance program (foodborne) appropriate and clearly defined to meet the objectives of the NOFO? (including sufficient detail to provide food safety programs with information to assist them with control of risk factors to illness and outbreaks)
- Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Is the plan for establishing and operating the EHS-Net well described and appropriate to meet the objectives of the NOFO?
- To what extent does the applicant describe how they will function as part of a national network of EHS-Net sites?
- How much experience does the applicant have as part of a national network of EHS-Net sites?
- To what extent does the applicant describe their ability to conduct research activities or projects are consistent with the guiding principles of the network as well as that addresses the needs and characteristics of the proposed EHS-Net site (i.e., demographic or language)?
- To what extent does the applicant clearly identify the proposed organizational and operating structures and the procedures for EHS-Net activities?
- To what extent 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.)

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?

- To what extent has the applicant demonstrated that they have the authority and responsibility to regulate retail food service establishments in their jurisdiction and deliver and implement retail food safety programs, evidence-based interventions and policies, and investigate foodborne outbreaks?
- Does the applicant describe whether/how the proposed work will relate to other programs sponsored by the agency or other agencies, which are already in place or planned to support foodborne disease surveillance and food safety?
- Are all of the partnerships necessary to complete the proposed project (including the establishing and operating the EHS-Net) supported by letters of support or memoranda of understanding that include detailed information about the nature of the relationships?

- Is the nature of and extent of each entity's involvement sufficient for the successful completion of the project as a whole?
- Does the applicant provide letters of support indicating each collaborators' commitments to participate in the EHS-Net, and describing their anticipated role on the proposed research?
- Do the letters of support or memoranda of understanding clearly describe the working relationships and level of involvement (including roles and responsibilities) between the applicant and the partner organizations?

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 (<https://www.cdc.gov/grants/additionalrequirements/ar-1.html>).

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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf) and the policy on the Inclusion of Persons Under 21 in Research (<https://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 four 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) 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 4) 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 (<https://grants.nih.gov/grants/olaw/VASchecklist.pdf>).

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.

Dual Use Research of Concern

Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: <http://www.phe.gov/s3/dualuse>. Tools and guidance for assessing DURC potential may be found at: <http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx>.

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 Plan(s)

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: <https://www.cdc.gov/grants/additionalrequirements/ar-25.html>

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The [AR-25](#) outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

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/grants/interestedinapplying/applicationresources.html>

The budget can include both direct costs and indirect costs as allowed.

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of \$25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

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 NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- 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.
- Applicant's governmental authority and responsibility to regulate and oversee retail food service in their jurisdiction. The success of this research is directly related to the applicant's ability and capacity to implement public policies and regulations to protect communities from foodborne outbreaks and to provide communities with safe food.
- Applicant's authority and responsibility to deliver and implement retail food safety programs, evidence-based interventions and policies, and investigate foodborne outbreaks.
- Applicant's experience functioning as part of a national network of EHS-Net sites.
- The applicant's capacity to implement public policies and regulations to protect communities from foodborne outbreaks and to provide communities with safe food.

- Applicant's ability to lead collaborative efforts to change or improve the delivery of environmental health programs developed for this NOFO's purpose.
- Geographic balance of proposed projects to broaden the reach of interventions to protect communities from foodborne outbreaks across the Nation.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or 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 NOFO 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 (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/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.

Recipient 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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

Specific requirements that apply to this NOFO are the following:

Generally applicable ARs:

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

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)
[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-19: Third Party Agreements & ATSDR \(AR-19\)](#)
[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](#)
[AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)
[AR-34: Language Access for Persons with Limited English Proficiency](#)
[AR-36: ; Certificates of Confidentiality](#)

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](#)

Paperwork Reduction Act / Information Collection:

Applicants are advised that any activities involving information collection (i.e., posting similar questions or requirements via surveys, questionnaires, telephonic requests, focus groups, etc.)

from 10 or more non-Federal entities/persons, including states, are subject to Paperwork Reduction Act (PRA) requirements and may or may not be subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) prior to the start of information collection activities. PRA applicability will depend on the level of CDC involvement with the development, collection, and management of information/data.

CDC Assurances and Certifications:

All applicants are required to sign and submit “Assurances and Certifications” documents indicated at <http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm>. Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications on an annual basis, name the file “Assurances and Certifications” and upload it as a PDF file at www.grants.gov or
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at:
[http://wwwn.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.asp](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/Homepage.asp)

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

Changes to Certificate of Confidentiality (CoC)

All Certificates of Confidentiality (CoC)s issued in the past or in the future by the CDC, must comply with the new requirements of subsection 301(d) of the Public Health Service Act as amended, especially the new disclosure requirements and restrictions.

1. The new disclosure requirements prohibit disclosure of the name of research subjects or any identifiable research information, document, or biospecimen to anyone not connected with the research except under very specific circumstances including:
 - If required by other Federal, State, or local laws, such as for reporting of communicable diseases;
 - If the subject consents;
 - Or for the purposes of scientific research that is compliant with human subjects regulations.
2. For studies in which informed consent is sought, CDC expects investigators to inform research participants of the new protections and the limits to protections provided by a CoC. CoCs will now automatically cover any CDC-funded project collecting or using identifiable, sensitive information that was new or on-going as of December 13, 2016.
 - The CoC will apply as a term and condition of award
 - There will be no physical certificate issued
3. Automatic coverage of a CoC means that institutions and investigators do not need to apply for a CoC. However, institutions and investigators are responsible for determining whether research they conduct is subject to subsection 301(d) of the Public Health Service

Act.

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.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html>.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, 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 website, www.usaspending.gov. For the full text of the requirements, please review the following website: <https://www.frs.gov/>.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 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>.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible

through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at <http://www.phe.gov/s3/dualuse>.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the

institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)

CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, “public health data” means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled “Open Data Policy–Managing Information as an Asset” (OMB M-13-13); Executive Order 13642 titled “Making Open and Machine Readable the New Default for Government Information”; and the Office of Science and Technology Policy (OSTP) memorandum titled “Increasing Access to the Results of Federally Funded Scientific Research” (OSTP Memo).

The AR-25 <https://www.cdc.gov/grants/additionalrequirements/ar-25.html> outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: <https://www.cdc.gov/grants/additionalrequirements/ar-36.html>.

4. Cooperative Agreement Terms and Conditions

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 award recipients 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 recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

This NOFO is for a cooperative agreement. Under the cooperative agreement mechanism, the Centers for Disease Control and Prevention's (CDC) purpose is to support the award recipients' 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.
- 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 grant recipient 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.
- Award recipients 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.

Post award, **CDC/NCEH staff** will work with successful applicants on the following activities:

- Coordinate EHS-Net and promote applicants' integration and involvement in EHS-Net.
- Identify, develop, conduct multisite research projects, and analyze and disseminate the findings from those projects, in a collaborative effort with EHS-Net partners.
- Provide guidance in implementing human subjects', Privacy Impact Assessment and Paperwork Reduction Act requirements.
- Provide feedback on individual site projects.
- Coordinate an annual EHS-Net Award Recipients Meeting to discuss and prioritize network activities.

- Monitor and evaluate EHS-Net activities and accomplishments in meeting its goals by conducting site visits and conference calls with successful applicants.
- Conduct environmental assessments during outbreak investigations and report data from those environmental assessments to NEARS.

Areas of Joint Responsibility include:

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

Common Rule Requirements

On September 8, 2015, the Department of Health and Human Services (HHS) and 15 other federal departments and agencies published a notice of proposed rulemaking (NPRM) proposing revisions to each agency's codification of the Federal Policy for the Protection of Human Subjects, originally promulgated as a Common Rule in 1991. On January 19, 2017, HHS and other federal departments and agencies published a final rule revising the Federal Policy for the Protection of Human Subjects. (82 FR 7149).

(<https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>)

The 2018 Common Rule Update has new requirements for cooperative research at Title 45 Code of US Federal Regulations, Part 46, and creates a requirement for U.S.-based institutions engaged in cooperative research to use a single Institutional Review Board (IRB) for that portion of the research that takes place within the United States, with certain exceptions. (<https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>)

Successful awardees under this cooperative agreement will be subject to the new rules, including the need to collaborate in selecting a single IRB to review and approve all non-exempt human subjects research activities conducted under this cooperative agreement.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see <https://grants.nih.gov/grants/rppr/index.htm>; https://grants.nih.gov/grants/forms/report_on_grant.htm) 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 recipients 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 recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients 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 (<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

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**, is due 90 to 120 days before the end of the current budget period. The RPPR form (<https://grants.nih.gov/grants/rppr/index.htm>; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. 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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) 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 period of performance.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress

reported on the RPPR form in eRA Commons (<https://grants.nih.gov/grants/rppr/index.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.
- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.
- Additional Reporting Requirements:

Technical Review Statement Response Requirements

Grant recipients will be required to electronically submit a response to the peer reviewers' comments and/or concerns, as appropriate, within 30 days of the notification of their initial award. Grant recipients will also be required to electronically submit a response to any progress concerns or areas for improvement noted on their annual Technical Review, within the time period specified in the annual award continuation notice.

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.

The due date for final FFRs will continue to be 90 days after the Period of Performance end date. Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients 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 recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.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: <https://grants.nih.gov/support/index.html>

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (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: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to <https://commons.era.nih.gov/commons> 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: https://era.nih.gov/docs/Commons_UserGuide.pdf.

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 period of performance. 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.
- **Final Data Management Plan:** Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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)

Email: ogstims@cdc.gov

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

Scientific/Research Contact(s)

Daniel Holcomb

Scientific Program Officer

for the National Center for Environmental Health, ATSDR, and NCIPC
Centers for Disease Control and Prevention (CDC)

Telephone: 770-488-1556

Email: dwh6@cdc.gov

Peer Review Contact(s)

Mikel Walters, PhD

Scientific Review Officer for RFA-EH-20-001

National Center for Environmental Health, ATSDR, and NCIPC
Centers for Disease Control and Prevention (CDC)

4770 Buford Hwy, NE, Mailstop S106-9, Atlanta, GA 30341

Telephone: 404-639-0913

Email: NCIPC_ERPO@cdc.gov

Financial/Grants Management Contact(s)

Mary Pat Shanahan

Grants Management Officer

Office of Grant Services

Centers for Disease Control and Prevention (CDC)

Telephone: 412-386-4453

Email: mpu0@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities 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.

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

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 grant recipients may 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). Specific authorities granted will be detailed in the official Notice of Award document.

Applicants are encouraged to pay close attention to the Responsiveness Criteria and the Data Management Plan requirements listed in the NOFO and to keep these in mind while preparing their proposals.

RFA-EH-20-001; Amendment 1

Environmental Health Specialists Network (EHS-Net) - Practice Based Research to Improve Food Safety

Questions and Answers from the Pre-Application Conference Call held on January 7, 2020

Please note that the questions and answers below do not represent an actual transcript of the Pre-Application Call.

The information below has been edited to be concise and to provide the best accuracy and clarity.

Q1: What is meant by the term, “ a positive statement of your intent to apply for a grant under this NOFO” in the Letter of Intent portion of the NOFO? Does this just mean we need to simply state that we intend to submit an application and include the NOFO number?

A1: Yes. That’s exactly what it means, but please also include the additional information that we request, including information on your intended research or proposed investigation. This helps us more efficiently and accurately select appropriate peer reviewers.

Q2: In section IV (5) of the NOFO for Research Plan Component it states, “some of the following components are for Resubmissions or Revisions only.” What does this mean?

A2: This is standard or “boiler-plate” language that refers to the resubmission of an application previously-submitted to this NOFO. Since this is considered a “NEW” NOFO, this would not apply to the initial applications submitted.

Q3: For recipients who are currently funded under EHS-Net NOFO EH-15-001, how would successful recipients under this new NOFO be handled to avoid the approximate one-month overlap of the project period for current grants with the expected start date of this new NOFO? Would existing grant recipients need to budget for only 11 months in the first year of this new

program?

A3: All applicants need to provide budget and project information for all five years, in anticipation that level funding will be available for all five years. We will adjust the start date for grants under NOFO EH-20-001 to September 30, 2020 to avoid any conflicts.

Q4: Regarding duplication of effort, what must we report?

A4: This refers to the situation where more than one funding source may be providing support to a recipient under this NOFO. Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. If this is anticipated, the applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap." If the expected overlap is due to the start date of a new award under this NOFO, please Q3, above.

Q5: Is there an expectation to document "in kind" resources? To what extent does CDC want these documented in our applications?

A5: We encourage partnerships between grant recipients and other state and/or local agencies. The Research Objectives in this NOFO specifically state that, "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." Applicants should include as much of this information as possible, including 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, for the consideration of the reviewers.

Q6: Do you want to see in kind dollar amounts documented in our applications, or are percentages enough?

A6: Since in kind contributions are meant to complement, not supplant, the grant recipient's award, the documentation of such support is up to the applicant, and a percentage of time or effort should suffice for the purposes of determining how such support will contribute to the expected success of the proposed research. It will be important for all applicants to make clear that the amount of effort listed for all staff will be sufficient to perform the staff members' roles in the proposed research activities.

Q7: Can you confirm who would be considered "key personnel" to be included in the

application?

A7: The application section for senior/key personnel and other significant contributors usually includes the Principal Investigator(s), other investigators, and anyone else who may be essential to the performance of the research activities proposed. The PD/PI(s) are always considered senior/key personnel. The PD/PI(s) should designate other personnel as senior/key if they contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

Q8: Do we need to include just the first year budget projection in our applications or estimated budgets for all five years of the project?

A8: The application process will ask all applicants to give budget projections for all five years of expected funding. However, 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.

Q9: If we are already involved in national studies, do you want applicants to include how they are already involved or do you just want a general statement such as, “we will be involved in all future CDC/NCEH studies”.

A9: Applicants should include both descriptions of involvement in their applications. The NOFO specifically includes the expectation that successful grant recipients will participate in both individual and multisite studies and programs, and the inclusion of previous involvements in your applications will give the peer reviewers information regarding how your past experience may contribute to your future performance and meet CDC/NCEH’s research needs.

Applicants are strongly encouraged to pay close attention to the Responsiveness Criteria and the Application Review Criteria listed in the NOFO and to keep these in mind while preparing their proposals.

Q10: On page 4 of the notice under Funds Available and Anticipated Number of Awards the FOA states there will be up to eight awards with an annual budget of \$192,587. On page 14, the FOA states that the Anticipated number of Awards is 8 but goes on to say that you anticipate funding 9 awards with an annual budget of \$193,000.00. Which is correct?

A10: The correct number of anticipated awards is eight, with an annual budget of \$192,587 per award. The award ceiling amount was correct on page 14. This discrepancy has been corrected in Amendment 1 of the NOFO.